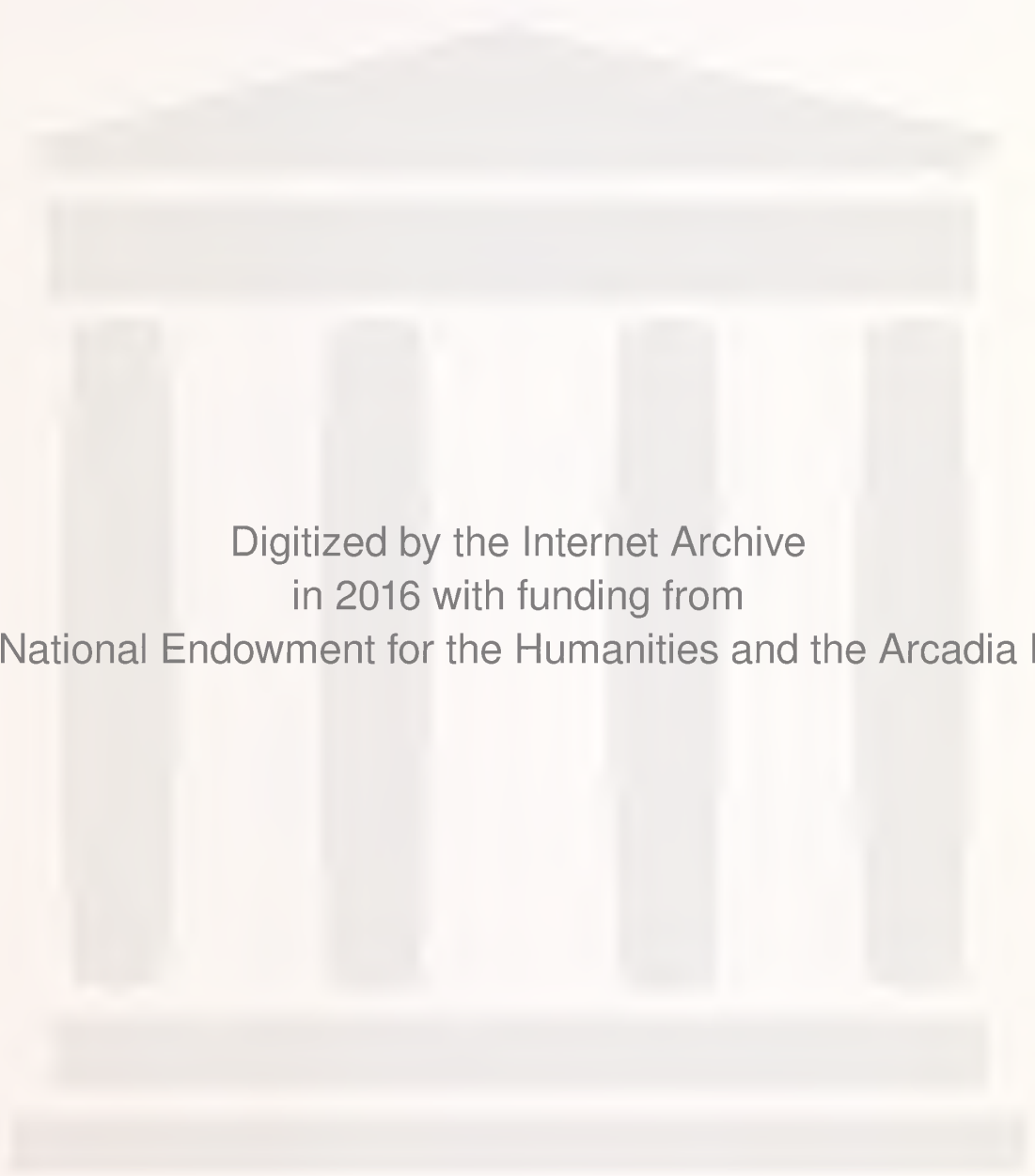




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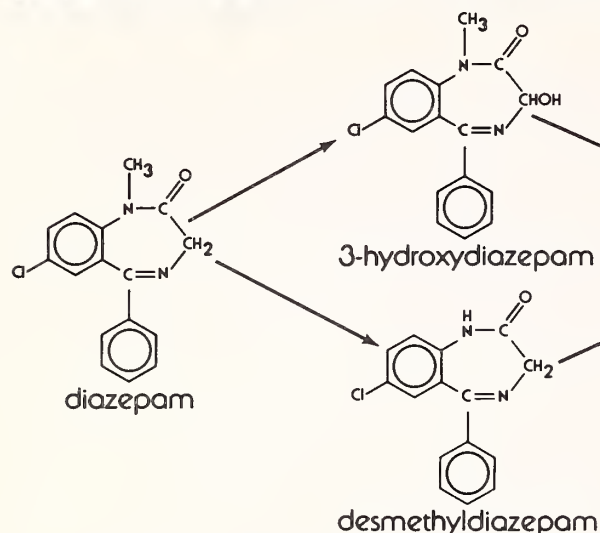
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Hepatic Portoenterostomy for Biliary Atresia

John H. Seashore, M.D.

Biliary atresia has long been one of the most frustrating problems in pediatric surgery. Difficulties in diagnosis, controversy about the role of early laparotomy, the dismal results of attempted surgical correction, and the agonizing downhill course and death of these patients have all contributed to a feeling of helplessness when faced with this unusual entity. The introduction of hepatic portoenterostomy by Kasai has been the most promising innovation in years. We wish to report our first experience with Kasai's operation and review the accumulated experience with hepatic portoenterostomy.

Historical Background

The differential diagnosis of prolonged obstructive jaundice in infants is extensive. Most of the uncommon causes can be excluded by conventional clinical and laboratory methods. In the great majority of infants one is left with a choice between biliary atresia and severe neonatal hepatitis which occur with about equal frequency. Despite a rash of new diagnostic techniques it is not possible to distinguish between these two entities by clinical or laboratory means. Operative cholangiography is the only method to establish with certainty whether the extra-hepatic bile ducts are patent. If biliary atresia is found, the prognosis is extremely poor. In a series of 843 cases collected by the Surgical Section of the American Academy of Pediatrics,¹ only 102 patients (12%) had a type of atresia correctable by conventional surgical techniques; that is, a patent segment of the extra-hepatic biliary tree which was in communication with the intrahepatic ducts and could be anastomosed to the gastrointestinal tract. Furthermore, only 53 of these 102 patients were long-term survivors; most of the others died of progressive cirrhosis and hepatic failure despite surgical correction. Over the years a variety of procedures have been proposed for "inoperable" patients. Insertion of silver and plastic tubes in the substance of the liver,^{2,3} placement of tubes at the porta hepatis to establish an external biliary fistula,³ partial hepatectomy with hepaticojunostomy⁴ and attempts to decompress the biliary tree through the hepatic lymphatics^{3,5} have all totally failed to produce sustained bile flow or long-term survivors with normal lives.

Our own experience reflects the national series except for a higher percentage of "correctable" cases.

JOHN H. SEASHORE, M.D., Assistant Professor of Surgery and Pediatrics, Yale University School of Medicine.

Presented before the annual meeting of the Connecticut Society of American Board Surgeons, December, 1975.

As shown in Table 1, we have seen 12 patients with biliary atresia in the past 13 years. Four (33%) had a patent common hepatic duct which was anastomosed to the gastrointestinal tract. Two (17%), operated at six weeks and four months of age respectively, are long-term survivors with normal growth and development and apparently normal livers, although one has an enlarged spleen. The other two, explored at 13 weeks and 5½ months, had advanced biliary cirrhosis and died, one of postoperative sepsis, the other of progressive hepatic failure. All eight patients with complete macroscopic obliteration of the extra-hepatic biliary tree died of progressive hepatic failure at 4½ to 46 months of age.

The overall 5% salvage of patients with biliary atresia and the report by Thaler and Gellis⁶ which suggested an increased incidence of late cirrhosis among infants with neonatal hepatitis who underwent laparotomy and cholangiography led many pediatricians to delay referral of infants with obstructive jaundice. After the age of four months, most infants with hepatitis were improving while those with biliary atresia continued to be jaundiced and were referred for exploration. Unfortunately, this policy ignored the data from the Academy of Pediatrics survey which showed that, of the operable patients, most of the 50% who were long-term survivors had been operated on under two months of age before the establishment of irreversible biliary cirrhosis.

Against this background it is not surprising that Kasai's initial report⁷ of successful hepatic portoenterostomy was greeted with considerable skepticism. However, the number of cures by Kasai and other Japanese pediatric surgeons has increased steadily and Lilly and Altman in this country have reported encouraging early results.⁸ We, therefore, undertook hepatic portoenterostomy in a recent patient who is the subject of this report.

Case Report

This male infant was the 3400 gm. product of a fullterm uncomplicated pregnancy and delivery. Abdominal distention was noted at four hours of age. Radiographs revealed pneumoperitoneum and he was transferred to this institution. Physical examination was normal except for abdominal distention. Intravenous fluid and parenteral antibiotic therapy were instituted. Laparotomy revealed antenatal jejunal volvulus with atresia of the involved segment. The end of the proximal jejunal segment was open and the source of the pneumoperitoneum. The end of the distal jejunum was sealed. End-to-end jejunojejunostomy was performed. An apparently small intrahepatic gallbladder was noted but no further exploration of the right upper quadrant was done. The postoperative course was complicated by episodes of sepsis

Table 1

YALE-NEW HAVEN MEDICAL CENTER					
BILIARY ATRESIA					
1961-1974					
	<i>Age at Operation</i>	<i>Findings</i>	<i>Procedure</i>	<i>Liver Biopsy</i>	<i>Result</i>
1. W.B.	4½ mos.	cordlike ducts	none	cholestasis; cirrhosis	died-46 mos.
2. J.W.	4½ mos.	cordlike ducts	none	"early cirrhosis"	died
3. P.D.	4 mos	absent GB & CBD; dilated CHD	choledocho- duodenostomy	"cirrhosis"	A&W-11 yrs.
4. M.P.	8 wks.	cordlike ducts	tube sewn to porta hepatis	cholestasis; early cirrhosis	died-19 mos.
5. A.R.	7 wks.	cordlike ducts	tube sewn to porta hepatis	cholestasis	died-9 mos.
6. J.S.	13 wks.	atresia distal CBD	cholecysto- jejunostomy	biliary cirrhosis	died-4 mos.
7. S.W.	12 wks.	cordlike ducts	tube sewn to porta hepatis	cholestasis	died-18 mos.
8. J.T.	4 mos.	cordlike ducts	tube sewn to porta hepatis	"consistent with hepatitis" early cirrhosis	died-4½ mos.
9. C.B.	6 wks.	atresia distal CBD	choledocho- duodenostomy	early cirrhosis	A&W-5 yrs. splenomegaly
10. E.W.	8 wks.	cordlike ducts	none	_____	died-54 mos.
11. C.B.	12 wks.	cordlike ducts	none	early cirrhosis	died-5 mos.
12. J.S.	5½ mos.	atresia distal CBD	choledocho- duodenostomy	biliary cirrhosis	died-8 mos.
CBD= common bile duct		CHD= common hepatic duct	GB= gallbladder		

ultimately traced to a left subphrenic abscess which drained spontaneously through the abdominal incision. Despite this intra-abdominal infection the infant passed green meconium stools on the fourth day and thereafter had normal, but acholic, stools and tolerated oral feedings. Jaundice was first noted on the fifth day of life (total bilirubin 5.70 mg/dl, direct bilirubin 4.0 mg/dl). Serologic studies for Rh and ABO incompatibility were negative as were appropriate tests for rubella, toxoplasmosis and cytomegalic inclusion virus. His serum bilirubin steadily rose as did the serum levels of hepatic enzymes (Figure 1). Initially the jaundice was attributed to sepsis but when direct hyperbilirubinemia persisted after drainage and resolution of the abscess, the possibility of biliary atresia was considered. An I¹³¹ Rose Bengal scan showed no evidence of excretion of dye from the liver at 24 hours: (Figure 2). At five weeks of age he was re-explored. The entire extra-hepatic biliary tree was replaced by fibrous cords with no visible lumen when transected. The common hepatic duct was traced to its entrance into the liver at which point a 1 cm. circle of Glisson's capsule and a small amount of hepatic parenchyma were excised. The jejunum was transected just distal to the ligament of Treitz and the proximal end anastomosed to the jejunum 10 cm. distal to the point of transection to create a Roux-Y loop. The free end of this loop was brought through the transverse mesocolon and sutured to the defect in the liver with a single layer of interrupted 5-0 silk sutures. Each suture was placed through Glisson's capsule and through all layers of the jejunum, taking care to invert the mucosa. The mid-portion of the Roux-Y loop was exteriorized as a side vented enterostomy. Figure 3 shows the details of the operative procedure.

Liver biopsy obtained at this operation revealed focal cholangiolitis, cholestasis and proliferation of bile ducts but no cirrhosis (figure 4).

Bile first appeared through the jejunostomy on the tenth postoperative day. A steady flow of 30-100 ml of bile a day has continued to the present. Liver function tests are summarized in Figure 1. Serum bilirubin concentration declined, rapidly reaching near normal levels by the tenth postoperative week. Serum glutamic-oxalic transaminase and alkaline phosphate rose initially and have followed a variable course. Serum 5' nucleotidase, which may be the most precise indicator of biliary obstruction, has fallen steadily but has not yet reached normal values.

His postoperative course has been complicated by gastrointestinal problems. When feedings were first offered, most of the formula came out the enterostomy. When measures to control this reflux were unsuccessful, the jejunojejunostomy was moved to make the Roux-Y loop 30 cm. in length. Reflux of feedings did not recur but the patient developed intractable diarrhea. There was no radiologic evidence of short bowel syndrome or stricture of the anastomoses. Diarrhea did not improve when he was given formula with medium chain triglycerides as the only source of fat. On breast milk feedings without refeeding of bile he excreted 75% of ingested fat; with refeeding of bile, 25% of ingested fat was excreted. Oral tolerance tests using glucose (10 gms) and fructose (3 gms) led to watery stools with acid pH. Over the next four months he was treated with two courses of total parenteral alimentation and gained weight steadily. He is currently tolerating an oral mixture of casein hydrolysate, medium chain triglycerides and sucrose.

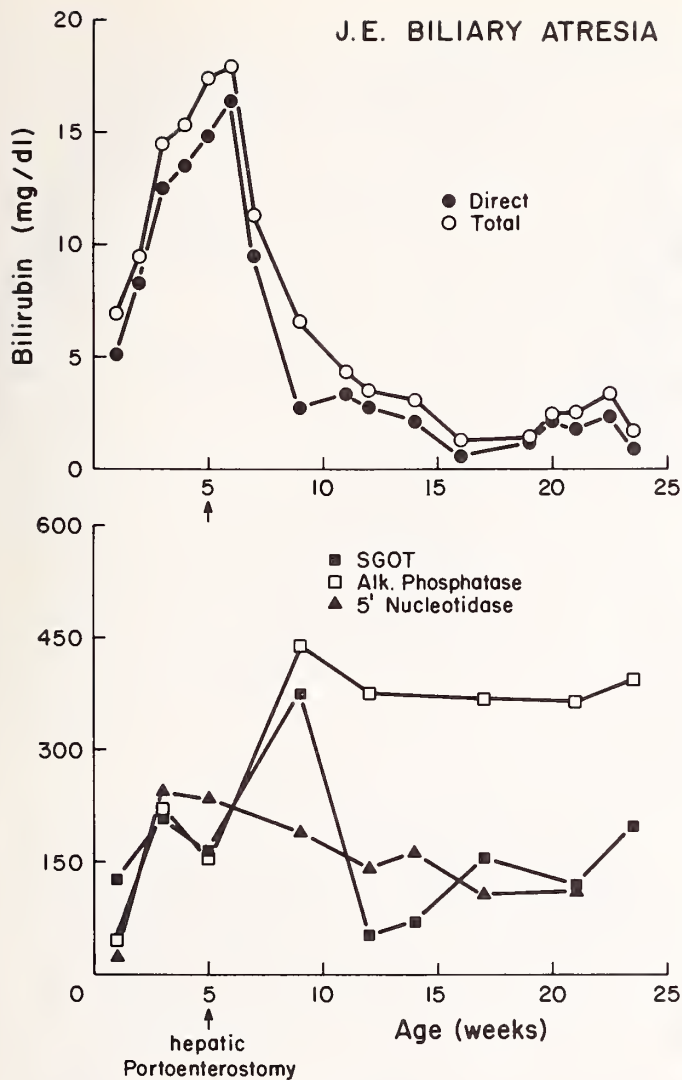


Figure 1

Serial liver function test before and after hepatic portoenterostomy.



Figure 2

Preoperative I^{131} Rose bengal scan shows no excretion of dye from the liver at 24 hours.

Discussion

Hepatic portoenterostomy has been performed in several hundred patients with an overall survival of about one in four of these previously incurable cases



Figure 3

Roux-Y hepatic portoenterostomy. The side-vented enterostomy in the jejunal loop prevents reflux of intestinal contents up to the area of anastomosis.

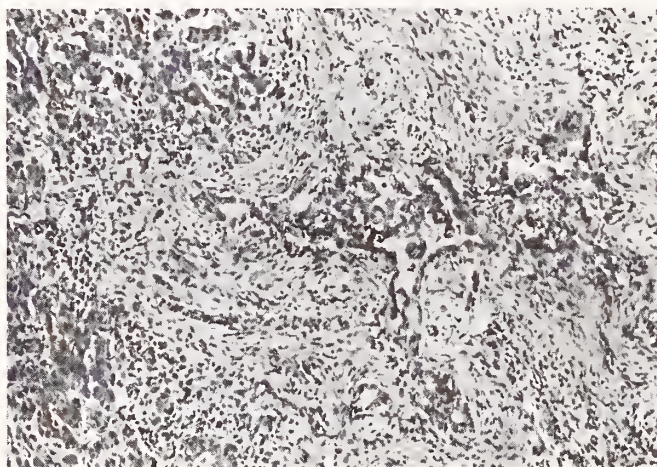


Figure 4

Liver biopsy obtained at the time of portoenterostomy. Cholestasis, periportal fibrosis and proliferation of bile ducts are present but there is no cirrhosis.

(Table 2). Two factors probably explain the success of this procedure compared to the failure of other techniques. First, portoenterostomy allows for antegrade rather than retrograde flow of bile through the intrahepatic ductal system. Second, sustained bile drainage is dependent on establishment of a mucosa to mucosa anastomosis. While this cannot be created surgically with microscopic ducts, the presence of dilated intrahepatic ducts at the area of

Table 2

HEPATIC PORTOENTEROSTOMY FOR BILIARY ATRESIA

<i>Age at operation</i>	<i>No. of patients</i>	<i>Satisfactory bile flow</i>	<i>Jaundice-free 1 year or more</i>
Under 3 months	135	82 (61%)	57 (42%)
Over 3 months	102	33 (32%)	7 (7%)
Total	237	115 (51%)	64 (27%)

Results of hepatic portoenterostomy from Lilly and Altman and the combined Japanese experience as collected by Bill (Progress in Pediatric Surgery, V. 6, p. 2, 1974).

anastomosis provides the opportunity for an autoanastomosis. Kasai has demonstrated by serial sections of the porta hepatis that most infants with biliary atresia have dilated bile ducts in this area, and that the size of these ducts correlated directly with the probability of achieving sustained bile flow.⁹ In his series of 39 patients, bile ducts larger than 200 μ in diameter were present at the porta in 22, and 17 of them had sustained bile drainage. The bile ducts in the other 17 patients were all smaller than 200 μ and only four of these patients achieved sustained bile flow. Suruga has confirmed the importance of duct size in relation to bile drainage.¹⁰ Lilly has shown by transhepatic cholangiography that an autoanastomosis does take place between the dilated intrahepatic ducts and the jejunal loop.⁸

The technical details of hepatic portoenterostomy are dictated by these observations. The cord-like atretic ducts are traced to the porta hepatis and transected as a portion of Glisson's capsule is excised. Lilly recommends frozen section examination of the excised tissue at the porta; if bile ducts are absent or less than 150, a deeper excision can be done.⁸ Since a true mucosa to mucosa anastomosis may not be achieved for several weeks postoperatively, the hepatojejunal anastomosis must be constructed to minimize inflammatory reaction and scarring which might obliterate the tiny ducts. Precise placement of fine sutures with careful inversion of the mucosa is essential. A two layer anastomosis may help to prevent bile leakage. Drains are not used.

As shown in Table 2, satisfactory bile flow and initial decline of serum bilirubin occurs in 50% of patients but only about half of these are long-term "cures". Some of these late relapses undoubtedly represent failure of establishment of a mucosa-to-mucosa anastomosis. Of greater importance, however, is ascending cholangitis which occurs in a significant percentage of these patients. The infection and bile stasis associated with cholangitis can cause progressive obliteration of the intrahepatic ducts and stricture of the anastomosis particularly in the first

few weeks before mucosal continuity is established. The optimal length of the Rous-Y loop is not known but it should probably be at least 30 cm.⁹ Cholangitis occurs even with long limbs, however, and it has become clear that more complete separation of the biliary and gastrointestinal tracts is necessary in the early postoperative period. The various procedures which have been described for this purpose are shown in Figure 5. There is inadequate information at present to know which technique will most effectively prevent cholangitis with least risk of other complications, such as fluid and electrolyte depletion from complete bile diversion.⁹ The enterostomy is closed three to six months postoperatively when sustained bile flow is established and serum bilirubin is normal. Cholangitis occurring after this time is less likely to cause obliteration of the anastomosis but has been incriminated as a cause of the progressive cirrhosis discussed below. Unexplained fever, rise in serum bilirubin and decreased bile flow are the hallmarks of ascending cholangitis. Prompt hospitalization and treatment with intravenous antibiotics and choleretics are indicated.

Progressive cirrhosis after "successful" portoenterostomy has been well documented. In all series, a significant number of patients with satisfactory bile flow and resolution of jaundice have become jaundiced again and died of hepatic failure from six months to two years postoperatively. Altman et al reported followup liver biopsies in 11 patients who were clinically well three to 23 months after portoenterostomy.¹¹ Eight showed a greater degree of hepatic fibrosis than at the time of operation; two were unchanged and only one was improved. Kasai reported followup liver biopsy in 12 patients two or more years after portoenterostomy.¹² Hepatic fibrosis appeared to resolve slowly over several years but often did not resolve completely. Unequivocal biliary cirrhosis developed in three patients one of whom had portal hypertension at eight years of age. Miyata et al have reported a high incidence of portal hypertension among their surviving patients.¹³

Kasai believes that the degree of hepatic damage at the time of portoenterostomy and the occurrence of cholangitis are the most important determinants of ultimate hepatic function.¹² Altman and Lilly also emphasize the role of cholangitis (seven of their 11 patients had one or more episodes of cholangitis) but point out that progressive hepatic deterioration can occur in the absence of cholangitis. They were unable to find any correlation between the degree of hepatic disease at time of operation and the progression or stabilization of changes in hepatic morphology.¹¹

All authors have emphasized the relationship of age to prognosis after portoenterostomy, which is shown

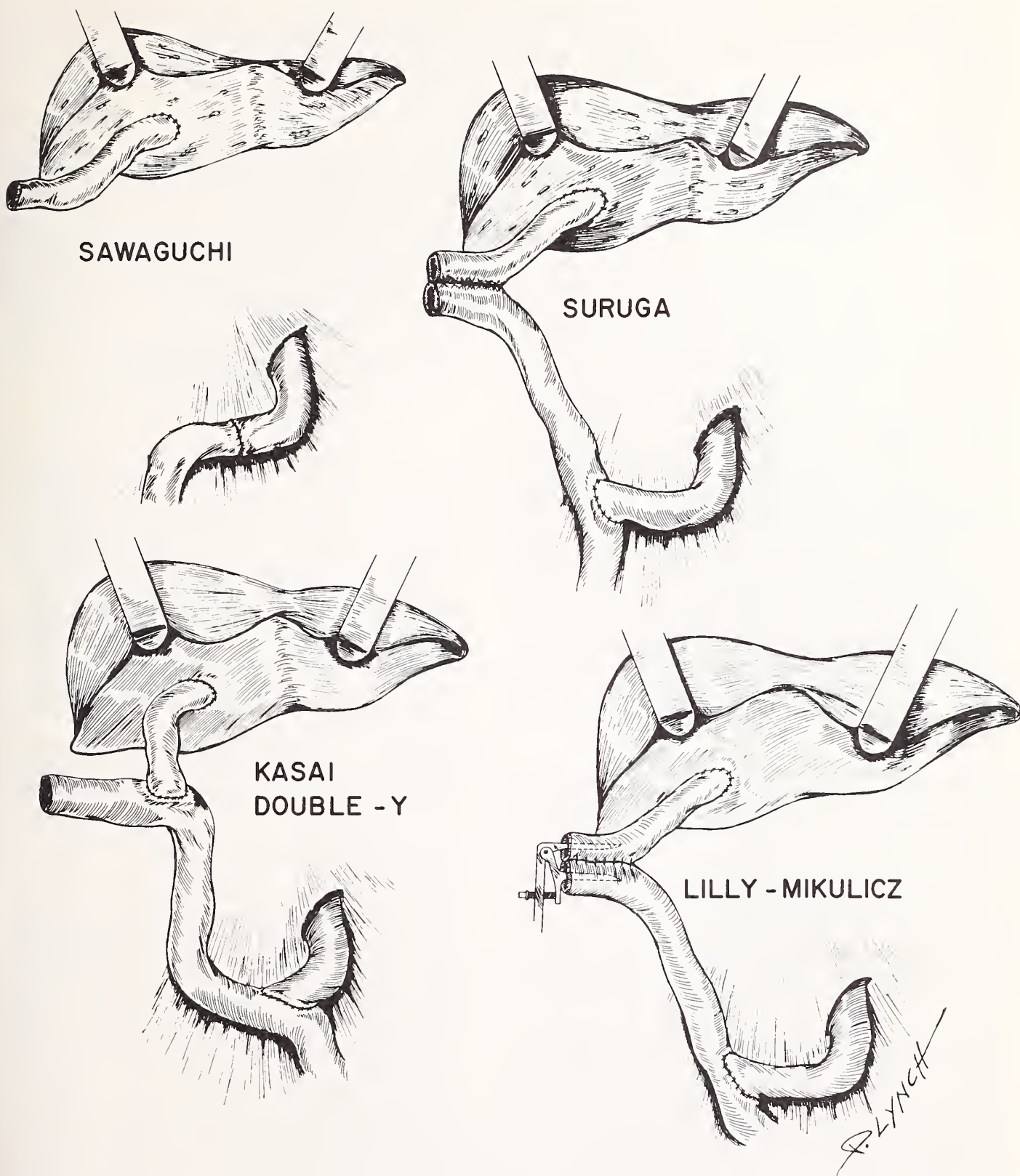


Figure 5

Techniques for temporary biliary diversion reported by four pediatric surgeons.

in Table 2. Infants over the age of three months at time of portoenterostomy are only half as likely as infants under three months to achieve satisfactory bile drainage and have even less chance of long term cure. This poor prognosis largely reflects the high incidence

of established biliary cirrhosis in untreated patients with biliary atresia after three months of age. Early exploration of infants with sustained obstructive jaundice is essential to achieve the maximum benefit from hepatic portoenterostomy.

While the size of bile ducts at the porta hepatis, age at operation, the degree of hepatic damage at time of operation and postoperative cholangitis are all important in determining prognosis after portoenterostomy, other factors must contribute. Some young patients with relatively normal livers and no cholangitis have nonetheless developed progressive cirrhosis after successful Kasai procedures. Biliary atresia and neonatal hepatitis share many clinical and histological features and are frequently indistinguishable on these grounds. Progression and regression of ductal obliteration and apparent transition from neonatal hepatitis to biliary atresia have all been reported. Landing, among others, argues persuasively that the two entities are different manifestations of the same acquired disease, presumably a viral infection. He proposed the term "Infantile obstructive cholangiopathy" to emphasize the dynamic nature of the disease.¹⁴ If this concept is correct, it is easy to understand why some patients with biliary atresia develop progressive cirrhosis after "successful" portoenterostomy and otherwise favorable conditions. Persistent viral infection in these infants causes continuing hepatic destruction and obliteration of intrahepatic ducts just as it does in a significant percentage of patients with neonatal hepatitis. Whether adequate decompression of the biliary tract by portoenterostomy has any effect whatsoever on the underlying disease process remains conjectural.

Our patient illustrates a number of points raised in this discussion. Hepatic portoenterostomy at five weeks of age led to sustained bile flow and fairly prompt resolution of jaundice. The liver biopsy showed cholestasis and proliferation of bile ducts but no fibrosis or cirrhosis. Bile ducts approaching 200 diameter were noted in the porta hepatis. Persistent elevation of serum concentrations of hepatic enzymes is compatible with slow resolution of the underlying disease but suggests the possibility of continuing hepatic destruction which may culminate in cirrhosis. This could be the natural history of the disease in this patient according to Landing's concepts, but could also be the result of two transient episodes of cholangitis. Parenteral alimentation is known to cause cholestasis and may be a contributing factor.¹⁵

The cause of his chronic malabsorption and diarrhea is not known. Diarrhea has not been reported as a complication of portoenterostomy. Diarrhea did not improve with refeeding of bile or the use of a medium chain triglyceride formula. He clearly had malabsorption of carbohydrate as well as fat. Prolonged malabsorption has been reported in patients following repair of intestinal atresia but diarrhea usually occurs immediately rather than after a

period of relatively normal gut function. A protracted period of total parenteral nutrition has appeared to allow restitution of the absorptive capacity of his gastrointestinal tract.

Summary

Eighty to ninety percent of infants with biliary atresia are incurable by standard surgical techniques. Hepatic portoenterostomy, introduced by Kasai, appears to offer the hope of salvaging perhaps one-third to one-half of these patients. A five week old infant who has had a successful early result from Kasai's operation is presented. The rationale, technical details, complications and results of portoenterostomy, and the relationship of biliary atresia to neonatal hepatitis are discussed.

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Concepts and Controversies about the Prevention of Coronary Heart Disease

Henry Blackburn, M.D.

The Potential for Prevention

The basic facts which represent the potential for prevention of ischemic heart disease (CHD) are no longer controversial. There are large differences in the frequency of CHD between cultures (Figure 1). This basic fact provides the potential for prevention.

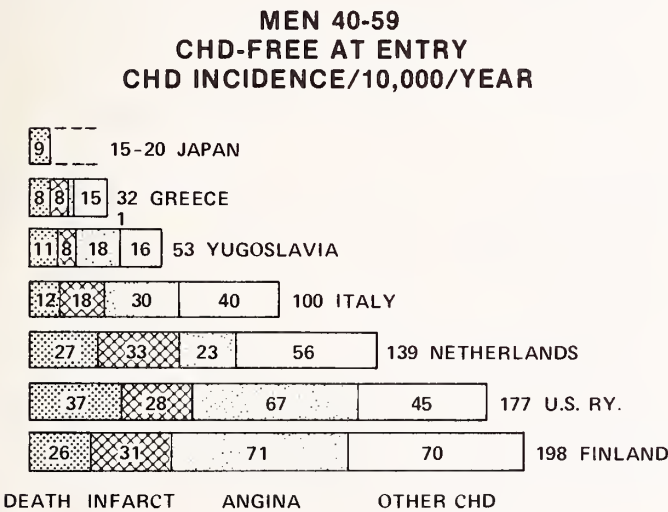


Figure 1

Age-standardized average yearly CHD incidence rates per 10,000. 12,529 men, aged 40-59, judged to be free of CHD at the outset. (Keys, A., ed.: Coronary heart disease in seven countries. Circulation, 41: Suppl. 1, 1970.)

The next basic fact in this picture is the monotonous consistency and congruence of evidence from many studies, around the world, that individuals in apparently good health have vastly different future risk of developing manifest coronary heart disease. Prediction equations separate individuals at 10 times different future coronary risk as computed from the “big three” risk factors, hypertension, cigarette smoking and serum cholesterol (Figure 2).

Controversy about Diet

Now let’s touch briefly on some of the controversies about risk factors and prevention which I will introduce by quotations from distinguished physicians. “When we look for good links between diet and serum cholesterol, we find they can’t be correlated too well.” This is an example that much of the controversy is unnecessary and misdirected; it evolves

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COMBINED RISK FACTOR SCORE AND FIRST CORONARY EVENT MEN 40-59

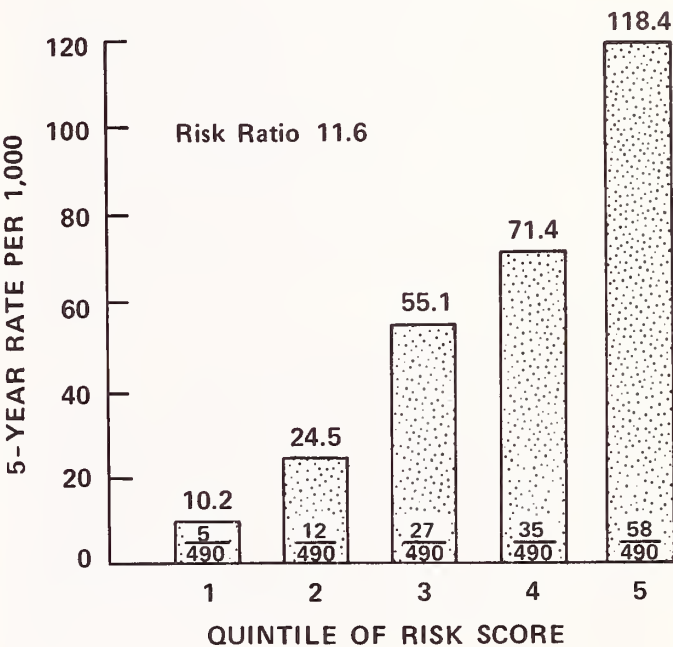


Figure 2

Computed from entry levels of systolic blood pressure, serum cholesterol, and number of cigarettes smoked daily. (Keys, A., ed.: Coronary heart disease in seven countries. Circulation, 41: Suppl. 1, 1970.)

from a basic difference in the physician’s clinical approach to problems and the preventive approach. It may help to separate individual cases with their individual risk from the population and its risk, i.e., risk characteristics of a population as distinct from those of the individual.

Correlations between *average* saturated fat composition in the habitual diet and average serum cholesterol levels found in populations are very strong where diets are analyzed chemically, during all seasons of the year. Correlations on the order of 0.9 exist between diet fat components and serum cholesterol levels. So this diet-cholesterol correlation is extremely good when measured in an objective fashion, in contrasting populations. Within a given culture people eating the same diets can have different serum lipid levels. This is due to intrinsic individual regulation of lipids. But the fact that there are inherent differences in the regulation of serum lipids in no way negates the overall importance of a dietary influence on those levels, in individuals and whole populations.

There are several reasons why the correlations between diet and serum cholesterol levels (or diet and coronary disease), may be weak *within* a given culture, such as within the U.S. One is that the measuring tool is extremely poor, for 24-hour recall or 3- or 7-day diet diaries are simply inadequate ways of measuring the diet of an individual. Secondly, in using such tools the variability of diet so measured in the individual is about as great as the variability in diet *between* individuals. In such a situation, it is simply mathematically impossible to demonstrate any sharp relationship between the factors being measured. So the measure itself and the natural variation in diet prevent an effective study of the question. Moreover, measuring the individual diet once or twice or even four times by such a method is hardly an adequate measurement of the *lifetime* habitual dietary experience which contributes to serum cholesterol level (and presumably to atherosclerosis). Finally, another important factor is the relative homogeneity of a national diet; e.g., the hallmark of the American way of eating is a high fat, high calorie diet. Contrasts of natural diets are more interesting as a means of studying the relationship between diet and serum cholesterol levels. Figure 3 gives the proportion of fat calories in the habitual diets in various of the Seven Countries Study, diets measured chemically, systematically in the Minnesota laboratory. Note that the primary difference between fat composition in these countries is in the saturated fat. The characteristic of countries with high average cholesterol levels and high coronary disease rates is a saturated fat composition over 15% of calories, as in the U.S., Finland and the Netherlands. The characteristic of countries with extremely low serum cholesterol levels and CHD rates, Japan and Greece, is saturated fatty acid composition under 10% of calories. Again, the correlations between saturated fat and serum cholesterol levels and coronary disease are really quite strong. These correlations are not discounted by any other similarly careful and systematic work that I know of.

Finally, we can hardly deny a strong correlation between diet and serum cholesterol if we consider what happens to serum lipid levels from experimental *changes* in diet. In Minnesota, on the basis of over 120 carefully controlled isocaloric substitutions of different fats in the diet, it is possible to predict mathematically the serum cholesterol response from a change in diet in small groups of people, expressed in an equation (2S-P). This indicates that the cholesterol raising power of saturated fatty acids is approximately twice as efficient as the cholesterol-lowering power of polyunsaturated fatty acids and that the contribution of dietary cholesterol is significant but may be largely

AVERAGE % CALORIES FROM FATS
MEN 40-59

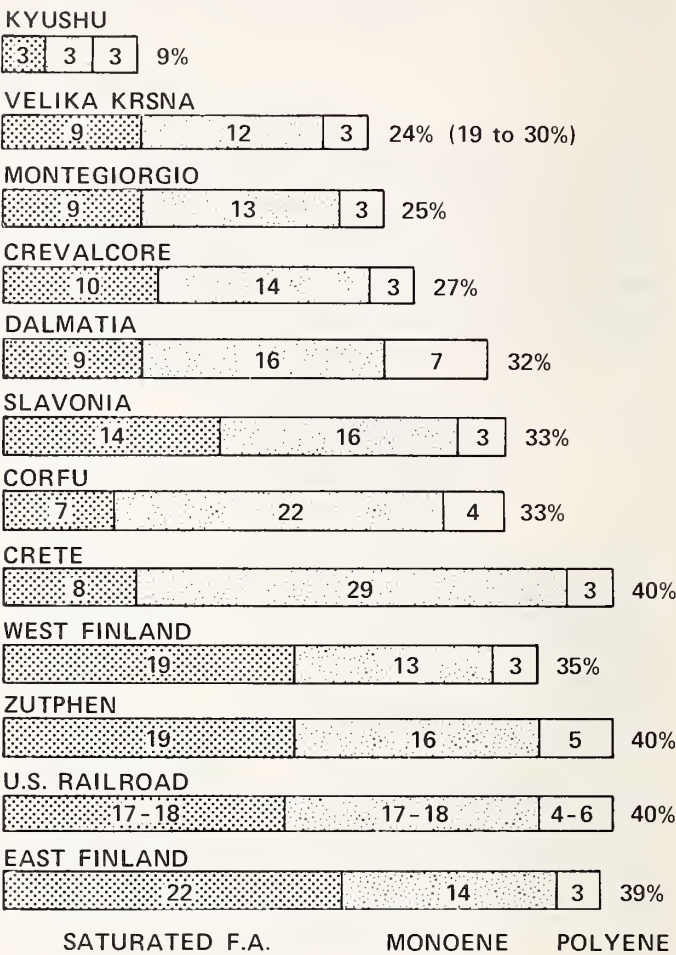


Figure 3

Average percentage of dietary calories provided by saturated, monoene, and polyunsaturated fatty acids. (Keys, A., ed.: Coronary heart disease in seven countries. Circulation 41: Suppl. 1, 1970.)

overwhelmed in high fat diets by the saturated fat contribution.

Polyunsaturated Fats

Another issue raised in Figure 3 is the question of polyunsaturated fats. I quote a West Coast physician, "Polyunsaturated fats are toxic; they cause premature aging and wrinkling of the skin and may accelerate atherosclerosis". Figure 3 indicates the generally similar level of polyunsaturated fat intake in a number of countries which differ greatly in serum cholesterol level and in CHD incidence. There is no correlation at all between average polyunsaturated fat intake and average serum cholesterol or coronary disease rates. Note also that in no country eating these natural diets is there an intake of polyunsaturated fats over 7% of calories; so obviously higher "poly" intakes are not "essential" to a low population rate of coronary disease. I doubt the "toxicity" idea but see no reason to distort the American diet by an excess of polyunsaturates.

Carbohydrates

Another common diet controversy has to do with carbohydrates. We hear a lot about carbohydrate-induced hyperlipidemia and the need for “low-carbohydrate diets”. The controversy, here again, involves singular and short-term observations in individual patients within our particular high fat eating culture and an unawareness of the experience in the larger world outside hospital and outside our particular culture. In Table 1 is a highly relevant long-term observation which deals with Japanese in Japan,

Table 1

PREVALENCE OF SERUM CHOLESTEROL ELEVATION (≥ 260 mg %) IN JAPANESE MEN*			
RATE PER 1000 MEN			
Age	Japan	Hawaii	California
45-49	27.9	131.4	138.9
50-54	33.9	135.8	198.4
55-59	30.6	132.7	161.0
60-64	27.1	127.1	160.5
65-69	27.6	73.8	189.5
Age Adjusted Rate	→ 31.6	124.0	162.5
No. of Men	→ 2138	7961	1816

PREVALENCE OF SERUM TRIGLYCERIDE ELEVATION (≥ 280 mg %) IN JAPANESE MEN*			
RATE PER 1000 MEN			
Age	Japan	Hawaii	California
45-49	79.5	272.1	278.4
50-54	64.5	278.8	269.4
55-59	62.0	242.9	251.9
60-64	38.4	180.5	262.2
65-69	41.1	193.5	187.5
Age Adjusted Rate	→ 61.4	245.5	251.9
No. of Men	→ 1815	7658	1825

*Marmot, M.G., et al., APHA, New Orleans, November, 1974.

in Hawaii, and in California, similar genetically, in which the frequency of elevated serum cholesterol (over 260 mg.%) varies from 31 per 1,000 in Japan, to 124 per 1,000 in Hawaii, to 162 per 1,000 in the Japanese in California. Notice also that in the Mainland Japanese who subsist on one of the highest carbohydrate diets of civilized industrial nations, the frequency of hypertriglyceridemia in middle-aged men is on the order of 6% whereas in the Japanese in

California on a lower carbohydrate diet, it's on the order of 25%. The lesson is that people who are subsisting on long term high carbohydrate and low fat diet often do not have hypertriglyceridemia. On the contrary, they have hypolipidemia by our standards.

Let's consider the diet sugar controversy. Sugar intake is about as highly correlated with coronary disease incidence as is fat intake. The correlation between coronary diseases and saturated fat intake is on the order of .86 while the correlation with sugar is on the order of .8. However, the correlation of saturated fatty intake with sugar intake is also on the order of .8 or .9. Could this just be silly correlations like with the number of telephones and TV antennae? In fact, there is no congruent evidence between clinical-pathological observations, laboratory-experimental observations, and population-epidemiological evidence in the sugar-CHD question as there is in the matter of diet fats.

Serum Lipids

Let's consider briefly one aspect of controversy over serum lipids as risk indicators. And here I'd like to take another quotation from a distinguished vascular surgeon: “Most of my vascular disease patients have serum cholesterol levels within the normal range.” This technically correct comment may be considered in the light of Figure 4. We might think of these widely

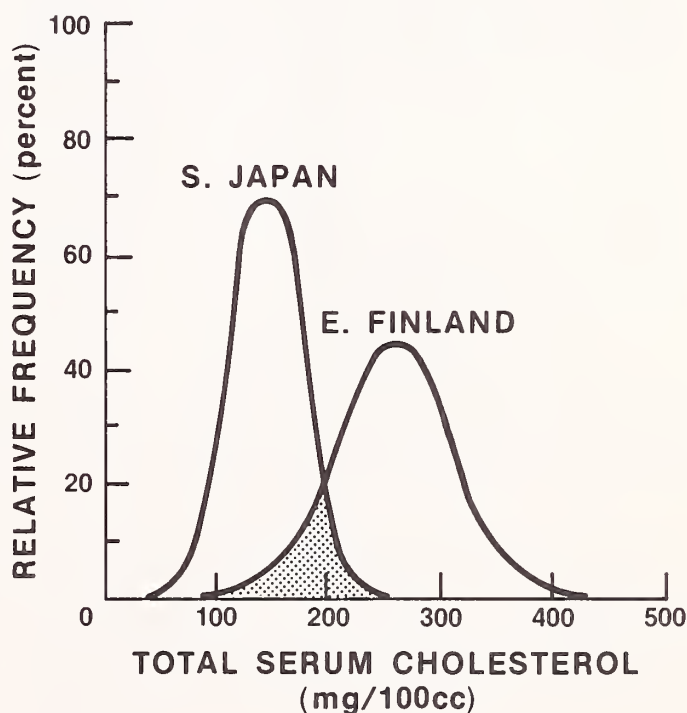


Figure 4

Distributions of serum cholesterol level in a sample of 504 men ages 40-59 in Ushibuka, Japan, and 775 men ages 40-59 in a sample from East Finland. (Keys, A., ed.: Coronary heart disease in seven countries. Circulation, 41: Suppl. 1, 1970.)

separate curves when we hear colleagues make such statements or when we catch ourselves saying, "Most vascular disease patients have normal cholesterol," or "This coronary patient has no risk factors." Obviously, a whole population may have relatively high lipids, and statistical norms in that population are not ideal norms in terms of actual CHD risk.

Heredity

Perhaps the most frustrating and useless controversy is that about heredity and coronary disease. Seeing a young person with a strong family history of coronary disease, with a clear-cut familial pattern of hyperlipidemia, with early angina pectoris, one is terribly impressed with the role of heredity in that individual and naturally so. But there is probably no way that epidemic or mass disease in entire cultures of millions of people can be attributed to mass inborn metabolic errors of fat metabolism. There is probably no way that the ten-fold differences in CHD between Finland and the U.S. versus Japan and the Mediterranean Islands could be explained by different hereditary make-up in these peoples. Distinct hereditary mechanisms are responsible for only a small proportion of the coronary disease in this country, where there is presumably an unfavorable environmental and cultural situation. There is no mass exhibition of inherited traits in the presence of a highly favorable environment. When there is a mass public health problem such as coronary disease, it cannot be explained usually by the genes; it is far more likely that society is "out of joint". Despite very great individual differences in intrinsic regulation of serum lipids, or in patterns of the coronary artery circulation, the *population* burden of coronary disease can be largely attributed to environmental, cultural, and thus potentially modifiable, influences, and this national burden is the concern of preventive cardiology.

High Risk Detection

Table 2 illustrates another concept which helps explain the controversy about a preventive practice for coronary disease. Note the equivalent risks in this

Table 2
EQUIVALENT CORONARY RISKS

<i>Cigarette Smoker</i>	<i>Serum Cholesterol mg./dl.</i>	<i>Systolic Blood Pressure</i>
0	400	<120
0	<200	250
+	260	140

Table between the individual who stands out as high risk, having a serum cholesterol level of 400 mg/dl. Notice that a man of the same age, having a low cholesterol value and at an equivalent risk otherwise,

would have a blood pressure reading of 250 systolic. Now in each of these cases, detected on some routine examination or screen, the practitioner would be alerted immediately to the high risk status. On the contrary, how much attention would be paid to the pack-a-day smoker, with systolic pressure of 140 mm and a serum cholesterol value of 260 mg/dl? Would we not be inclined to pat him on the back, and tell him to "cut down a little," here and there, and come back and see us in six months for a blood pressure check? Yet this third man is at fully equivalent coronary risk to the other two, though not identified as having a high risk, either to himself or in the mind of the physician.

Behavior

There is a large area of controversy having to do with stress, personality and behavior. There is in fact the claim that Type A behavioral type is "the number one cause of heart attack" in a popular best seller of 1974. It is true that most of us consider that stress and behavioral response to stress may have something to do with a *propensity* to sudden death or coronary disease. But, number one cause for whom? For a man whose father died at 38 of a coronary, and who has tendonous xanthomas at age 26? I doubt that one can say that behavior is his most important risk factor. Or for a 2½ pack-a-day cigarette smoker, is it his cigarette smoking or his behavior, and is one dependent on the other? Or for a hypertensive, with a diastolic pressure of 114 mm, in say, a well-adapted railroad engineer with no sense of time urgency and in no chronic struggle with his system? One can hardly say that Type A behavior is his most important risk factor. And what about whole populations such as in the calm delightful civilization of the Finns; can one say that their rate of coronary disease (the highest on earth) is due to the fact that they are in constant struggle with themselves and their society and under time urgent, goal-less demands? At the opposite extreme are the overcrowded, intensive, time-urgent, aggressive, ambitious Japanese, not yet touched to any significant degree by the coronary epidemic. So neither from an individual standpoint nor from a population risk characteristic can behavior be "the most important cause" of coronary disease. Whether or not it operates over and above the main "known" coronary risk factors is now being actively explored. There is now a suggestion that in our culture there may be some independent contribution of behavioral type to risk. It remains to be seen whether, if measured, it can be changed, and whether, if changed, this would influence coronary risk, and whether this would operate independently or through action on dietary, smoking and other habits. For the moment, because of the limitations of the measurement and the failure to demonstrate whether behavior can be successfully

modified, the hypothesis remains an interesting, but still an untestable one. For the moment, we must pursue those risk factors for which the influence is clearly shown, those which are clearly measurable, and clearly modifiable. Certainly this evaluation must be made before publicly disclaiming that the "known" risk factors of blood pressure and smoking and serum lipids are largely irrelevant, or before claims are made that if one reduces all other risk factors and fails to change his behavior, he will come to naught.

Physical Activity

Physical activity is one of the more controversial of risk elements because it is very difficult to measure, or to modify experimentally, or to modify as a single risk factor without intervening rather strongly on a number of other risk characteristics when it comes to giving health advice to free-living populations. A number of investigators have pondered the problem of physical activity in coronary disease, have reviewed all of the data on occupational and leisure time comparisons, and have come to the conclusion that most of the data are consistent with a possible protective effect of activity. But in none of the studies is the design satisfactory. In none of the studies is it possible to eliminate bias, i.e., to be sure that the groups compared are similar in characteristics other than those of leisure or occupational activity. This leaves a full demonstration and test of the exercise hypothesis to an experimental trial. But because even under the best circumstances the relative contribution of physical activity is weaker than the other three risk factors, and because of the terrible difficulty of getting people into supervised exercise programs and adhering to them over the long term and the staffing and cost of such undertakings, it is the opinion of a number of investigators that a test of the activity hypotheses in primary prevention of coronary disease is not feasible in our time. We are thus left to extrapolate from our knowledge about the importance of locomotion and large muscle endurance activity and its tonic effect on the body, its psychic influence, its role in terms of energy balance, weight control and prevention of obesity, and to recommend moderation and regularity, without hesitation, for these reasons, rather than for scientific certainty that we're influencing the course of atherosclerosis or the likelihood of coronary event in our patients.

Other Professional Attitudes

Finally, let us consider a few other professional attitudes about prevention including the search for a "breakthrough." I must say that I have little faith that a scientific breakthrough is just around the corner which will enable us to dissolve or resolve atheroma or to safely and completely eliminate hypertension in the

next period. I would reverse the argument that implies we should invest less in sound attempts at prevention and more in basic research and maintain rather that we should have a balanced effort. At this time, because of the propitious moment, because of the importance and potential of prevention, we must systematically explore the results of risk factor reduction in our culture.

We should indeed face the issue squarely: suppose the preventive measures do not pan out to be terribly effective in the long term high risk middle-aged groups in which they are being tested? Similarly the results may not be impressive in tests of secondary prevention in post-infarction survivors such as in the Coronary Drug Project, the current studies on coronary artery surgery, on ileal bypass in myocardial infarction patients, and on physical fitness and rehabilitation of coronary patients. Conceptually, what reason have we to expect that intervention on primary risk factors, at advanced stages of atherosclerotic disease, in a widely and heavily involved population, could greatly reduce the rate of coronary events or sudden death, which must to a far greater degree be determined by the vascular and myocardial damage than by specific precipitating or atherogenic factors? What reason have we to expect to influence overwhelmingly the coronary risk in middle-aged men already in the upper tenth percentile of risk in our culture, itself highly set above others in terms of its risk characteristics? Is it reasonable to expect a 10, 25 or 50 percent decrease, by intervention on people at such an advanced stage of a multi-factorial and socio-cultural phenomenon?

The preventive effort underway is, of course, a calculated risk, necessary because if we started at ages where prevention might be expected to be more influential in terms of the atherosclerotic process, we would have the virtually impossible situation of intervening on very young people in long term ways which our society is not organized enough to arrange in effective experimental design. The greatest danger of the current generation of trials in high risk individuals is that the intervention will not be remarkably effective in lowering risk characteristics and this in turn will not be remarkably effective in reducing incidence. It remains to be seen if the prevention results are definitely positive or suggestive of a trend. If positive, I think we will move into the broader public health application of preventive measures. If, however, the results are clearly negative, in the very high risk, this would not disprove the major multiple risk factor hypothesis about the causes of ischemic heart disease and atherosclerosis, so clearly set out in other clinical, pathological and epidemiological evidence. But it will make it politically and practically very difficult to explore further these questions effectively in the

general population. We'll have to cross this bridge if we come to it. I consider it unlikely that multifactor primary intervention in high risk groups, reducing smoking, blood pressure and blood lipids, will prove *wholly* ineffective.

Social Changes

Finally, I'm inclined to be somewhat optimistic in terms of eventually changing professional and social attitudes along the lines of prevention. I have confidence that an informed profession and citizenry will undertake the social changes necessary in the agro-economy and in mores, to effectuate a substantial reduction in risk characteristics in the American population. The exciting "Three Town Study", a demonstration by Stanford University, suggests

already that the media message on health combined with screening and intervention on a target group of high risk individuals will effect substantial changes in attitudes, behavior, and risk factors levels in the community as whole.

The broadest, most socially aware statement of the profession about primary prevention of ischemic heart disease is to be found in the Inter-Society Commission of Heart Disease Report (Circulation, December 1970, revised in April, 1972 available in a 1975 update from the offices of that society, 44 East 23rd Street, New York, NY 10010). In my view this report presents a policy and promotes a strategy which an advanced society should implement in very studied and deliberate, but determined, steps.

Acute Suppurative Tenosynovitis: Role of Postoperative Irrigation of the Tendon Sheath

Sultan Ahamed, M.D.

Abstract—Pyogenic infection of the tendon sheaths presents an acute emergency. Management of these infections by immediate surgical drainage and postoperative irrigation of the tendon sheath with return of full function is illustrated here.

Acute suppurative tenosynovitis is uncommon today after the discovery of antibiotics. The improved results of treatment have been well documented over the past decades.^{1,2} The mechanism of infection is usually a penetrating wound of the tendon sheath. The majority of these take place at the flexion crease because the skin is devoid of much subcutaneous fat and the tendon sheath is thin. As these patients may have been given antibiotics before the infection spreads to the tendon sheath, the clinical presentation varies. The cardinal symptoms of the tendon sheath infection include excessive tenderness over the course of the sheath, symmetrical enlargement of the finger, pain on extension of the finger and flexed position of the finger. There are usually associated general effects like elevated temperature, axillary lymphadenitis and leukocytosis. Infections of the tendon sheath require immediate drainage. Making one long midlateral incision so as to drain the sheath widely was advocated by Kanavel and Bunnel.^{3,4} However, making small incisions at the proximal and distal ends of the tendon sheath followed by postoperative irrigation of the sheath has been used with complete return of function. Experience with the patients managed in such a manner is discussed below.

Clinical Data

Three patients were treated for pyogenic tenosynovitis of the finger. One patient had a puncture wound and the other two had lacerations of the finger. The duration between the injury and the onset of symptoms varied from six to fourteen days. All of them presented with the classical signs and symptoms of acute tendon sheath infection. The operation was performed under general anesthesia in the bloodless field. The distal end of the sheath was explored through a transverse incision at the distal crease of the finger. The proximal end of the tendon sheath was exposed through a small incision in the palm. The tendon sheaths were found to be bulging with purulent fluid. The synovial sheath was thickened. Small windows were made at both ends of the tendon sheath. The fluid was sent for bacteriological examination including sensitivity studies. A small catheter with multiple pinholes along the distal end was inserted through the proximal opening in the sheath and advanced to about the middle of the finger. Irrigation of the tendon sheath was performed with sterile normal saline followed by 0.25 percent Kanamycin solution. Two small Penrose drains were placed one each at the proximal and the distal wound. The wounds were then closed with interrupted nylon sutures (Figure 1). The hand was dressed and kept at rest for forty eight hours. The irrigation was continued four times a day with twenty to thirty ml. of 0.25 percent Kanamycin solution for two days at which time the catheter was removed and active movement of the finger were started. These patients also received cephalothin parenterally for two

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Figure 1

Catheter inserted into the tendon sheath. Penrose drains in place.

days and orally for five days more. The Penrose drains were removed on the fourth postoperative day. The bacteriological findings are summarized in Table 1.

Table 1
BACTERIOLOGICAL FINDINGS

Type	Resistant To Penicillin	Sensitive To Cephalothin	Sensitive To Kanamycin
Staphylococci Coagulase Positive ²	Yes	Yes	Yes
Streptococci B Hemolytic Group A ¹	No	Yes	Yes
Klebsiella pneumoniae ¹	Yes	Yes	Yes
Serratia marcescens ¹	Yes	Yes	Yes

Results: Two of the three patients regained full movements of the affected finger. One patient who had necrosis and loss of skin around the original injury required a small split thickness graft to the medial aspect of the index finger of the nondominant hand. In this patient, there was a ten degree flexion deformity of the distal interphalangeal joint and minimal restriction of flexion at the proximal interphalangeal joint. All patients are back at their normal work.

Discussion

Infection of the tendon sheath if not treated properly will lead to necrosis of the synovia. When that happens, the denuded tendons adhere to each other. Since it is essential to prevent the damage to the synovia, it is important to drain the sheath as quickly as possible.⁵ Ryan and Hoopes advocated needle aspiration of the digital sheath in aiding the diagnosis of tenosynovitis.⁶ Over 90 percent of infections in the hand are reported to be due to Gram positive organisms and of these almost 90 percent are Staphylococci.^{5,7} Eaton et al reported 76 percent of organisms cultured from hand infections to be Gram positive and 24 percent Gram negative. Of these the five most common organisms were Staphylococcus

aureus 47 percent; Betahemolytic streptococcus 17 percent; Enterococcus 10 percent and Escherichia coli 5 percent. Sixty-four percent of the staphylococci were resistant to penicillin.⁸ Stone et al reported Staphylococci to be responsible in 58.6 percent of organisms cultured in the infections of the hand and E. Coli in 8.3 percent.¹⁰

Empirical treatment of the hand infections are begun immediately and the antibiotics are changed if needed when the sensitivity study is available. As two out of three staphylococci are resistant to penicillin and one out of four organisms cultured is Gram negative, it seems advisable to start the patient on methicillin or cephalothin. Stone et al recommended the use of oxacillin or methicillin for Gram positive organisms and Kanamycin for Gram negative organisms. Irrigation of the tendon sheath with saline was recommended by Loudon et al.⁹ Entin felt that it was not possible to open up a tendon sheath adequately unless the incision extends its entire length; however, he suggested that the antibiotic installation appeared to shorten the period of morbidity.⁵ Kilgore et al advocated antibiotic irrigation with bacitracin 5,000 units in 500 cc Ringers' solution for two to three days. Pollen used penicillin for irrigation. Even though irrigation with saline by itself is the important factor in cleaning the tendon sheath, addition of an antibiotic to the irrigating solution for the first 48 hours of the postoperative period achieves a higher concentration of the antibiotic locally within the tendon sheath. This appears to clear the infection effectively and shorten the morbidity.^{2,5} Kanamycin, 0.25 percent, was used for irrigation in this series.

Summary

Acute tendon sheath infections respond well to immediate surgical treatment. The types of infection organisms seem to vary from Gram positive to Gram negative bacteria. Drainage of the tendon sheath was performed through two transverse incisions one at the distal crease of the finger and another at the palm. Postoperative management included irrigation of the tendon sheath through a fine catheter with 0.25 percent Kanamycin solution for two days. All patients had satisfactory recovery and return of function.

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Adult Respiratory Distress Syndrome: Current Perspective

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Abstract—Traditional concepts of pathophysiology of the adult respiratory syndrome are outlined. Controversy between “lumpers” and “splitters” is noted in order to bring this syndrome into current perspective for the family practitioner.

Introduction

We will review for the family practitioner the basic concepts of pathophysiology and physiologically oriented therapy in those clinical entities that have been “lumped” together under the term adult respiratory distress syndrome (ARDS).

Controversy

The term adult respiratory distress syndrome (ARDS) has served as a useful means of communication about a diverse group of clinical disorders manifested by marked respiratory distress, refractory hypoxemia, diffuse infiltrates on chest radiographs and stiff non-compliant lungs.¹

Currently there is controversy regarding continued use of the term ARDS versus abandoning the term and using specific clinical terms whenever possible.

Petty and his supporters point to the utility of the term in identifying a high risk group of patients and instituting appropriate intensive pulmonary management.²

He estimates that 150,000 cases are recognized each year and that 50% can survive by proper methods of management related to recognition of ARDS. Petty thus maintains that the term ARDS continues to be a valid description of a clinical syndrome with similar clinical, physiologic and pathologic features. Understanding these points provides for a physiologically oriented therapeutic approach.

Murray and his supporters argue for the eventual abandonment of the term ARDS and the use, when known, of the specific clinical entity. He maintains that when the etiology or pathogenesis is unclear one can

communicate in terms such as “acute pulmonary insufficiency associated with shock, pancreatitis, etc.”³

The above comments are made to project the concept that the nomenclature and concepts in this area are still in a process of evolution and are being further defined.

Traditional Concepts of Pathophysiology

The term ARDS has been used to describe a syndrome involving direct or indirect pulmonary insults that can lead to a clinical picture of:

1. Marked respiratory distress—with tachypnea, dyspnea and hyperventilation.
2. Diffuse infiltrates on the chest radiograph—an alveolar interstitial pattern with a normal cardiac silhouette.
3. Stiff non-compliant lungs requiring high pressures to ventilate the lung.
4. Impaired gas exchange and oxygen transport as indicated by refractory hypoxemia or a poor oxygenation ratio.
5. Post mortem findings of pulmonary congestion, hyperemia and hyaline membrane formation.

Some of the clinical entities that have been associated with acute pulmonary insufficiency and referred to by Petty as ARDS include:

1. direct chest trauma
2. shock associated with abdominal wounds, ruptured spleen, GI bleeds, pancreatitis
3. aspiration pneumonia
4. near drowning
5. viral pneumonias
6. massive fat embolism
7. gram negative pneumonia

Diffuse injury to the pulmonary capillary endothelium is the underlying mechanism leading to a damaged alveolar capillary membrane. The damaged alveolar capillary membrane has increased permeability and results in leaking of fluid into alveolar spaces. The fluid in the alveolar spaces results in a decreased surface area for alveolar capillary exchange.

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The fluid in the alveolar spaces causes interference with surfactant activity. Surfactant, a lipoprotein, is secreted by the type 2 granular pneumocyte.⁴ Surfactant lowers surface tension as alveolar spaces decrease in size during exhalation and prevents the collapse of alveoli as they become smaller during exhalation. The combination of alveolar and interstitial fluid and then the effects of decreased surfactant activity can lead to:

- 1. Stiff non-compliant lungs requiring high pressures for an adequate tidal volume and
- 2. Areas of atelectatic lung which are perfused but not ventilated resulting in physiologic shunting and hypoxemia.

Treatment

General principles of treatment involve

- I. Preventing alveolar collapse and maintaining oxygenation
 - (a) intubation or tracheostomy
 - (b) volume respirator
 - (c) strict control of inspired oxygen (FIO2)
 - (d) positive end expiratory pressure (PEEP)
- II. Preventing further injury
 - (a) control of inspired oxygen tension
 - (b) monitoring fluids to prevent a positive water load
 - (c) antibiotics for specific infections
 - (d) steroids when specifically indicated, i.e. fat embolism, aspiration or chemical pneumonias

Peep

During exhalation there is a natural tendency for alveoli to decrease in size and to collapse. Airway pressure falls to zero or atmospheric pressure and there would be no pressure gradient between airways and alveoli and therefore there would be a tendency for alveoli to collapse. In normal individuals surfactant stabilizes alveoli by decreasing surface tension as they decrease in size thereby maintaining patent alveoli. The fluid in alveoli and interstitium, in ARDS, not only directly causes atelectasis, but also damages the alveolar lining cell which secretes surfactant and thus further promotes atelectasis. PEEP prevents alveolar collapse by maintaining a pressure gradient between airways and alveoli during exhalation. The physician or respiratory therapist can attach a simple PEEP device to a volume respirator and by dialing the PEEP attachment can prevent exit of air from the exhalation port thus creating a positive pressure during exhalation. PEEP therefore maintains a pressure gradient between airways and alveoli during exhalation; airway pressure is not allowed to return to atmosphere—therefore maintaining patent alveoli and

increasing the number of alveoli that are available for the next inhalation.

Conclusion

Basic traditional concepts of pathophysiology and treatment of those entities, referred to under the term adult respiratory distress syndrome, have been reviewed. Terms and symbols pertinent to this syndrome and intensive respiratory care are cited. Current controversy between “lumpers” and “splitters” is also noted in order to focus this syndrome into current perspective for the family practitioner.

ALVEOLAR Ventilation (VA): The volume of gas moved in and out of functioning alveoli per unit of time.

COMPLIANCE: The change in volume per unit change in pressure. A small change in volume per unit change in pressure indicates low compliance or “stiff” lungs.

FIO2: Fraction of inspired oxygen, i.e. FIO2 =0.21 = 21% oxygen inspired air.

FUNCTIONAL RESIDUAL CAPACITY (FRC): The volume of gas in the lungs at the end of a normal tidal breath or exhalation when the respiratory muscles are relaxed.

HYPOXEMIA: A reduction in arterial oxygen tension (PaO2) and arterial oxygen saturation (SaO2).

HYPOXIA: Decreased availability of oxygen at the tissue level.

OXYGENATION RATIO: Ratio of oxygen tension in the arterial blood (PaO2) to inspired oxygen tension (FIO2)

$$\text{i.e. } \frac{\text{PaO}_2}{\text{FIO}_2} = \frac{90-100}{.21} = 4-5 \text{ in normal individual}$$

PaO2: Arterial oxygen tension (mm Hg) or torr.

PEEP: Positive end expiratory pressure.

PIP: Positive inspiratory pressure.

SURFACTANT: A lipoprotein believed to be secreted by the type 2 granular pneumocyte lining the alveolar capillary membrane. Surfactant helps maintain patency of airways during exhalation by lowering surface tension as alveoli decrease in size.

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Hypercalcemia: Diagnosis and Therapy

(This is the third of a series of five articles on calcium metabolism.)

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The frequent determination of the serum calcium concentration as part of routine screening in many laboratories has shown that hypercalcemia is much more common than was previously recognized. Although patients with mild hypercalcemia are often asymptomatic, marked hypercalcemia is potentially life threatening and its early recognition and treatment are of great importance.

As discussed in the first article of this series, serum calcium concentration is maintained within narrow physiologic limits by the concerted action of parathyroid hormone (PTH), the active metabolites of vitamin D, and calcitonin (CT) on bone, kidney, and the gastrointestinal tract.¹ Pathologic hypercalcemia usually occurs when bone resorption or gastrointestinal absorption of calcium are markedly increased. Increased renal tubular reabsorption of calcium probably does not initiate hypercalcemia, but helps to maintain it.

Causes of Hypercalcemia

The most frequent mechanism for hypercalcemia is excessive bone resorption. Even in those diseases where the major mechanism is increased gastrointestinal absorption of calcium, such as vitamin D intoxication, there may also be a component of increased bone breakdown. On the other hand, in hyperparathyroidism, where excessive bone resorption is the major mechanism, increased gastrointestinal absorption and renal tubular reabsorption of calcium also contribute to the hypercalcemia. We find it useful to classify hypercalcemia into two sub-groups based on whether increased bone resorption or gut absorption is the predominant mechanism because this helps us to plan a more rational therapeutic approach based on pathogenetic mechanisms.

A. Hypercalcemia due to increased bone resorption

1. Primary hyperparathyroidism

Primary hyperparathyroidism is caused by excessive secretion of PTH by abnormally functioning parathyroid glands. Eighty to ninety percent of cases are due to single parathyroid adenomas. A small number of patients have multiple adenomas, while about 10% of cases are caused by

hyperplasia of all four parathyroid glands. About 1% of cases have parathyroid carcinoma. Hyperparathyroidism may occur as one expression of the multiple endocrine neoplasia (MEN) syndrome. In Type I MEN syndrome it is associated with functioning adenomas of the pancreatic islet cells which may produce either insulin or gastrin and pituitary adenomas, which may cause acromegaly. In the Type II MEN syndrome, hyperparathyroidism is associated with medullary carcinoma of the thyroid and pheochromocytoma. In both instances the parathyroids often show either multiple adenomas or hyperplasia, and if a single adenoma is found initially, there is often recurrence in another gland.

Hyperparathyroidism may present with renal stones or bone disease, but is often found in patients who are asymptomatic or have non-specific complaints of fatigue and weakness. Symptomatic bone disease is rare in younger patients, probably because they can increase bone formation to keep pace with increased bone resorption. In older patients the bone formation response is impaired and osteopenia is a frequent manifestation of hyperparathyroidism. Hyperparathyroid patients can show unusual fatigue, myopathy with proximal muscle weakness, and a variety of mental changes. Essential hypertension, peptic ulcer, pancreatitis, hyperuricemia and pseudogout have all been reported to be more frequent in patients with primary hyperparathyroidism than in the general population. Some of these may be direct effects of high serum calcium concentration. Hypercalcemia and hypercalciuria can impair renal function in the absence of re-

Table I
CAUSES OF HYPERCALCEMIA CLASSIFIED BY
MAJOR PATHOGENETIC MECHANISM

<i>Increased Bone Resorption</i>
primary hyperparathyroidism
cancer with bone metastases
cancer without bone metastases
multiple myeloma
thyrotoxicosis
Paget's disease with immobilization
fracture with immobilization
<i>Increased Gastrointestinal Absorption</i>
vitamin D intoxication
milk-alkali syndrome
sarcoidosis
<i>Mechanism Unclear</i>
Addison's Disease

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nal stones resulting in impaired concentrating ability and decreased glomerular filtration.

Secondary hyperparathyroidism occurs as a result of prolonged hypocalcemia which stimulates PTH secretion and ultimately results in hyperplasia. Such patients do not ordinarily have hypercalcemia except when the original cause for stimulation of the parathyroid glands is removed. Under these conditions the hyperplastic glands are not turned off by the elevated serum calcium, but continue to leak excessive amounts of PTH. Persistent secondary hyperparathyroidism often produces hypercalcemia in patients with renal failure after transplantation.² This may persist for several months until the parathyroid glands involute.

2. Hypercalcemia of Malignancy

Although malignancy is the most common cause of hypercalcemia, the mechanism is still poorly understood in most cases. Even when there are bony metastases it may not be the direct bone destruction by malignant cells that is responsible. These tumors may secrete osteolytic factors which have not as yet been identified. Some tumors cause hypercalcemia without metastasizing to bone. These may secrete PTH-like factors and hence cause clinical manifestations indistinguishable from those of primary hyperparathyroidism³. Many tumors have been found to produce this syndrome, including squamous cell carcinoma of the lung, parotid carcinoma, reticulum cell sarcoma, adrenal adenocarcinoma, hypernephroma, hepatoma, ovarian, endometrial and gastrointestinal carcinomas. The evidence that these tumors synthesize and secrete PTH is often not strong and other osteolytic factors may be responsible. Prostaglandins have been implicated as the cause of hypercalcemia in certain tumors. These compounds stimulate bone resorption in tissue culture and are clearly the cause of hypercalcemia in certain animal tumors^{4,5}. Some patients with hypercalcemia of cancer respond to treatment with indomethacin, an inhibitor of prostaglandin synthesis. Moreover, some of these patients have been shown to excrete increased amounts of prostaglandin metabolites in the urine⁶. In myeloma and certain lymphomas associated with bone destruction and hypercalcemia, the tumor cells produce an osteoclast stimulating factor that causes bone resorption in tissue culture, does not appear to be a prostaglandin, and resembles the osteoclast activating factor secreted by activated normal human leukocytes.^{7,8} It is likely that still other as yet undiscovered substances will be found to be responsible for some forms of the hypercalcemia of malignancy.

3. Hyperthyroidism

Hypercalcemia is seen in 15 to 20 percent of patients with hyperthyroidism⁹. Thyroid hormones are known to increase bone turnover and have been recently shown to stimulate bone resorption directly, which could be responsible for hypercalcemia¹⁰. The elevation of serum calcium is mild or moderate and does not require emergency therapy. Hypercalcemia will respond to treatment of the thyrotoxicosis with antithyroid drugs or even, according to recent reports, with propranolol. An occasional patient will show persistent hypercalcemia, because they have coexistent hyperthyroidism and hyperparathyroidism.

4. Immobilization and Paget's Disease

Immobilization increases bone resorption relative to bone formation¹¹ and may increase calcium concentration in patients with high rates of bone turnover. Immobilization is most likely to produce hypercalcemia in patients with Paget's Disease or in young individuals, particularly adolescents, who are immobilized for fractures and have rapidly remodeling bones. Immobilization may also lead to hypercalcemic crisis in patients with hyperparathyroidism or myeloma who were previously only moderately hypercalcemic.

B. Hypercalcemia due to increased intestinal absorption

1. Vitamin D intoxication

Large amounts of vitamin D can increase serum calcium concentration both by stimulating absorption from the intestine and mineral mobilization from the bone. The toxicity of vitamin D₂ and D₃ is usually only seen after prolonged high doses on the order of 50,000 units per day or more, but when it does occur, the hypercalcemia may be sustained for months, presumably because large excesses of vitamin D have been stored. Vitamin D intoxication will probably occur more frequently as the more potent metabolites are released for general use. 1,25 (OH)₂D₃ can increase serum calcium in a few days, but conversely, serum calcium falls more rapidly with discontinuation of the drug. Currently vitamin D overdosage is seen rarely and only in individuals who are being treated therapeutically with the vitamin or in food faddists.

2. Sarcoidosis

Hypercalcemia that occurs in patients with sarcoidosis resembles that seen in vitamin D intoxication. Small doses of administered vitamin D produce supernormal increases in calcium absorption in these patients. This could be due either to an increase in end organ sensitivity to vitamin D metabolites or to an increased synthesis of such active metabolites. The serum concentration of 25 OH D has been reported to be normal in sarcoidosis. Hence, the ab-

normality probably does not result from increased intestinal absorption, or activation in the skin and liver of vitamin D, but could be due to excessive renal hydroxylation of 25 OH D to the more active metabolite, 1,25 (OH)₂D.

3. The milk-alkali syndrome

Hypercalcemia, mild alkalosis and renal insufficiency can occur in patients who take excessive amounts of calcium and alkali in the form of milk, calcium carbonate, and sodium bicarbonate over long periods¹². There may be a factor of host sensitivity since there are only occasional patients who regularly develop hypercalcemia after oral calcium loads. This syndrome has become much less frequent, probably because the commonly used antacids are now nonabsorbable.

The Differential Diagnosis of Hypercalcemia

The first diagnostic step is to determine whether hypercalcemia truly exists and how severe it is. This should be done with reference to serum total protein and albumin concentration. About half the total serum calcium is bound to protein and changes in protein concentration will alter total serum concentrations independent of the concentration of ionized calcium, the determinant of cellular effects. Although the amount of calcium bound is somewhat variable, a rough correction can be made based on the serum albumin concentration. Since albumin is the most important plasma binding protein and since the abnormality is usually in the form of hypoalbuminemia, we use the simple correction of increasing serum calcium by 0.8 mg/100 ml for every 1 g/100 ml that the serum albumin concentration is below the normal mean value of 4.0 g/100 ml.

Once the diagnosis of hypercalcemia has been established, it is important to determine the cause, so that effective therapy can be instituted. When hypercalcemia is life threatening, therapy and diagnostic work-up must be carried out simultaneously. In general, we attempt to lower the serum calcium concentration in any patient in whom it exceeds 15 mg/100 ml or in patients with severe symptoms. As we have described previously,¹³ many tests may be necessary to establish the diagnosis of primary hyperparathyroidism. The major abnormalities in addition to hypercalcemia, are hypophosphatemia, increased blood PTH, hyperchloremic acidosis, increased excretion of cyclic AMP and phosphate with decreased tubular reabsorption of phosphate, and hypercalcuria. In cases with bone disease, serum alkaline phosphatase is increased. Hypercalcuria is of limited diagnostic value in patients with hypercalcemia. It may be found no matter what the cause and actually may be less marked in

patients with primary hyperparathyroidism, because PTH increases tubular reabsorption of calcium. In addition to chemical studies, radiographs of the hands may show characteristic subperiosteal resorption. Unfortunately, none of these studies are diagnostic of hyperparathyroidism. Radioimmunoassays do not consistently separate normal individuals from hyperparathyroid patients. A normal value in the presence of a high serum calcium is considered consistent with primary hyperparathyroidism. If the immunoreactive PTH is very high and renal function is normal, this is most likely due to primary hyperparathyroidism, although conceivably it could be due to a malignant tumor which secreted a PTH-like peptide. Using all the available data which support the diagnosis as well as extensive studies designed to rule out other causes of hypercalcemia, it is possible to make a strong presumptive diagnosis and recommend neck exploration in most patients with primary hyperparathyroidism. The definitive diagnosis is made at surgery when each of the parathyroid glands can be examined pathologically. If a single adenoma is found and the remaining glands are normal or hypoplastic, the patient can be cured surgically. In patients with multiple adenomas or hyperplasia, recurrences are more common. In patients in whom the adenoma is not found at the original operation, reexploration should be preceded by attempts at localizing the source of PTH. Selective venous catheterization with PTH immunoassays may be helpful^{14,15} as well as arteriography and possibly thermography or scanning. At present we do not recommend such localization studies before initial exploration because their interpretation is uncertain, the techniques are difficult, and at least 80% of patients can be cured at the initial operation without such studies if it is done by a careful and experienced surgeon.

Studies to rule out other causes of hypercalcemia are at least as important as those directed towards making a positive diagnosis of primary hyperparathyroidism. If malignancy is suspected, then a bone scan and metastatic series should be obtained as well as relevant radiologic and laboratory studies directed toward finding the primary tumor. Serum thyroxine levels should be obtained in all patients and additional hormone measurements if the clinical situation warrants. In Paget's Disease, in addition to radiologic studies, bone scans, serum alkaline phosphatase, and the 24 hour urinary hydroxyproline excretion, are particularly helpful in assessing the extent and severity of disease and following the response treatment. Patients with vitamin D intoxication and milk-alkali syndrome are identified largely by history. Moreover, measurements of 25 hydroxy

vitamin D levels are now available and should be markedly elevated in vitamin D intoxication. These patients, as well as those with sarcoid, are quite responsive to glucocorticoids so that steroid therapy can be used as a diagnostic test.

The Therapy of Hypercalcemia

The initial therapy in patients with severe hypercalcemia is rehydration with normal saline. This will not only lower serum calcium concentration by dilution but increase urinary calcium excretion because proximal tubular calcium reabsorption is linked to sodium and the natriuresis of volume expansion is associated with calciuresis. Of course, fluid excess must be watched for, particularly in elderly patients with cardiopulmonary disease. In such patients, a central venous pressure line should be considered to monitor fluid replacement. Once rehydrated, the patient can be treated with a loop diuretic such as furosemide or ethacrynic acid which will increase urinary calcium excretion further ¹⁶. However, large doses may be necessary and the beneficial effects are often small and transient. If those potent diuretics are given without adequate and maintained hydration, or if they continue to act after salt replacement has been stopped, they can produce rapid salt and water depletion and a rapid increase in serum calcium concentration. Furthermore, diuretics are stop-gap measures which have no effect on the source of increased calcium, that is, increased bone resorption or gut absorption. Because we believe the hazards often outweigh the benefits, we do not recommend routine use of diuretics in hypercalcemia, but use them only early for their transient benefit in patients with extremely high serum calcium concentration.

Treatment of Hypercalcemia due to Increased Bone Resorption

The goal of therapy is to inhibit bone resorption, if possible. Two agents, calcitonin and mithramycin, are general inhibitors of osteoclastic activity which probably act in this manner. Two additional agents, glucocorticoids and neutral phosphate, may inhibit bone resorption as part of their effect but have important additional effects on calcium movements. Finally, in patients with metastatic carcinoma or carcinoma secreting an osteolytic factor into the circulation, therapy directed against the tumor itself can stop the increased bone resorption responsible for hypercalcemia. None of the available agents are ideal. We still do not have a non-toxic inhibitor of bone resorption which has a rapid, dependable, and sustained effect and is easy to administer and control.

a. Calcitonin

Calcitonin fulfills the requirements of being a non-

toxic inhibitor of bone resorption which acts rapidly, having its maximal effect within four hours. Moreover, it is easy to control and rarely causes hypocalcemia.

Table 2
RATIONAL APPROACH TO THERAPY FOR HYPERCALCEMIA

Rehydration With Normal Saline
For Bone Causes
Aim—inhibit bone resorption
Means—1. remove or treat cause
2. neutral phosphate
3. calcitonin
4. mithramycin
5. glucocorticoids
For Gastrointestinal Causes
Aim—reduce calcium absorption from gastrointestinal tract
Means—1. remove or treat cause
2. reduce dietary calcium
3. glucocorticoids

Unfortunately, however, it is seldom completely effective and may only reduce serum calcium concentrations by two to three milligram percent so that there is usually still hypercalcemia after therapy. Even this small response would be quite useful if sustained, but in many patients calcitonin only has a transient effect. In two to three days the serum calcium begins to increase again, presumably because the osteoclasts escape from calcitonin inhibition. This escape phenomenon can occur both in vivo and in vitro. It is probably due to a change in the sensitivity of the bone resorbing cells to calcitonin. In some patients, escape can be prevented by simultaneous administration of glucocorticoids.¹⁷ Our experience has been that escape is uniform with calcitonin alone and still occurs in about 50% of patients treated with calcitonin and prednisone together. Calcitonin is the most rapidly acting and safest drug we have for producing small decreases in serum calcium and can be used before rehydration is complete, unlike furosemide. Hence, our indication for calcitonin is in the acute therapy of severe hypercalcemia for its small, but rapid, effect and in chronic therapy in combination with glucocorticoids in those patients in whom phosphate or mithramycin are contra-indicated or have been ineffective.

b. Phosphate

Neutral phosphate, given either intravenously or orally, is uniformly effective in lowering serum calcium concentration, but the effect is fairly slow. The mechanism of action is complex; there may be direct inhibition of osteoclastic bone resorption, increased calcium deposition in bone and decreased calcium absorption from the gut. Unfortunately, soft tissue calcification can also occur, and is probably the mechanism for impaired renal function in some

patients treated with large doses of phosphate. Phosphate is used in hypercalcemic patients with normal renal function who have low or normal serum phosphate concentrations initially. To avoid soft tissue calcification, we ordinarily use only oral phosphate in doses of one to three grams of phosphorus per day. Even under these circumstances, we follow the serum phosphate, creatinine and blood urea nitrogen carefully, and if serum phosphate starts to increase or there is impairment of renal function, therapy is discontinued. Diarrhea is a troublesome side effect and may limit prolonged use of phosphate. It can sometimes be avoided by lowering the dose. Intravenous phosphate is rarely employed because it is more likely to produce extra-skeletal calcification, particularly in the kidney.

c. Mithramycin

Mithramycin is a potent inhibitor of DNA-dependent RNA synthesis, which was originally used as an anti-neoplastic drug and was incidentally found to lower serum calcium concentration. It is the most frequently used drug in the treatment of hypercalcemia due to malignancy. Its effects are powerful, but not rapid, taking a day or two to develop. It is somewhat harder to control in that it can produce hypocalcemia. Its mode of action is not clear but it appears to be toxic to bone resorbing cells in vitro and probably has a similar effect in vivo. The major disadvantage of mithramycin is its potential toxicity to other tissues. Even when given in relatively low doses of 15-25 ug per kg of body weight, the side effects may be cumulative so that with repeated doses, impairment of hepatic and renal function may occur. Mithramycin is particularly hazardous in renal failure because its excretion depends on glomerular filtration and it has a direct toxic effect on the kidneys. Despite these drawbacks, mithramycin is indicated when hypercalcemia is severe, when the patient has an inoperable malignancy, and when other agents are ineffective or contraindicated.

d. Glucocorticoids

Glucocorticoids are probably most effective in treating hypercalcemia due to increased intestinal absorption of calcium, but can be effective in some cases where increased bone resorption is the cause. Glucocorticoids are so rarely effective in primary hyperparathyroidism that the response to glucocorticoids can be used as a differential diagnostic test. These agents are strikingly effective in myeloma, sarcoidosis, and vitamin D intoxication and may be effective in some patients with carcinoma. In myeloma, the mechanism is most likely inhibition of the effect of osteoclastic activating factor-like materials on the bone. In other conditions, the effect on the intestine or on the primary lesion may be more important. The

major difficulty with the use of glucocorticoids is that the effects are not only variable, but relatively slow. It may take 7 to 10 days for the fall in serum calcium concentration to occur. In addition to being specifically indicated in myeloma and hypercalcemia due to increased gut absorption of calcium, glucocorticoids can be used in combination with calcitonin, as described above, in hypercalcemia of any cause.

Treatment of Hypercalcemia due to Increased Intestinal Absorption

Patients with hypercalcemia due to vitamin D intoxication, sarcoidosis, or milk-alkali syndrome absorb an increased amount of calcium from the gastrointestinal tract. The average American diet contains about 800-1,000 milligrams of calcium per day. Normally, only 10 to 30 percent of this is absorbed, but in these patients the proportion absorbed may increase to 50% or even higher. After treatment of any underlying cause, the first therapeutic maneuver in such patients should be restriction of dietary calcium. By limiting calcium containing foods and using demineralized or distilled water, intake can usually be reduced to less than 400 mg per day. In some patients this is sufficient to bring serum calcium concentration back to normal. However, in many it is advisable to use glucocorticoids, which are consistently effective in this form of hypercalcemia. Glucocorticoids presumably act by inhibiting calcium absorption from the gut directly and may also have an indirect effect by enhancing the degradation of the active metabolites of vitamin D.¹⁷

Conclusion

Hypercalcemia is a common, potentially life threatening clinical problem, which may be associated with increased bone resorption or increased calcium absorption from the gastrointestinal tract. The treatment should be based on the pathogenesis of the hypercalcemia and its severity. Although there are a number of agents available for treatment, none is entirely satisfactory and the search for more effective, reliable and less toxic drugs or combinations of drugs should continue.

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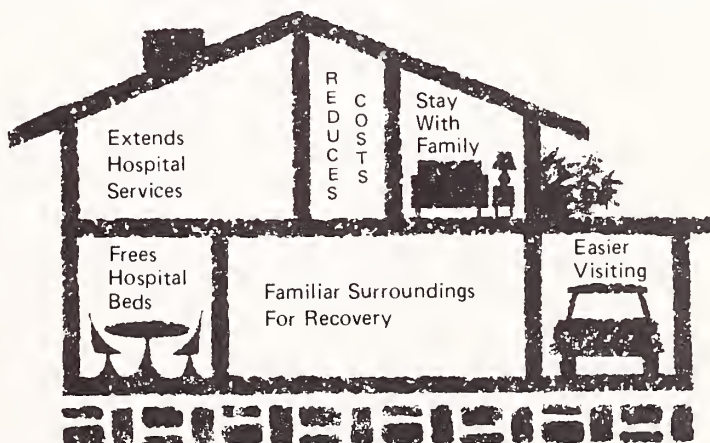
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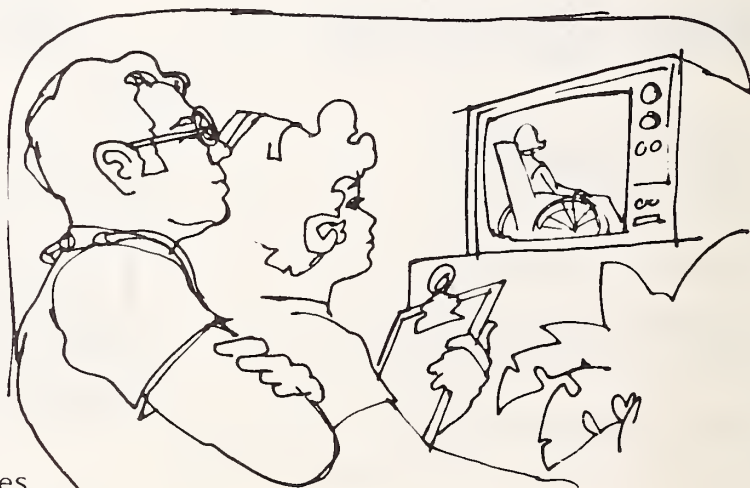
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Technology Assessment, the Congress, and Health

Emilio Q. Daddario

Our time for the application of science on a major scale, is approaching rapidly, and medicine will be totally transformed when it happens. The hard problem just ahead will be for us to set priorities and make choices between options. We will be obliged, as never before in our history, to select between alternative possibilities in technology . . .

Dr. Lewis Thomas, President
Memorial Sloan-Kettering Cancer Center

It could very well be that medicine is now at the technological threshold of a new era. Dr. Lewis Thomas, the articulate and perceptive former Dean of the Yale University School of Medicine, has cast "high" technology: as the force which has brought us to this position. The impetus has not come from "high" technology, such as the technical perfection of the pacemaker or of an artificial heart, but rather it stems from the remarkable advances in biomedical research over the past 25 years which in his opinion will soon dispel "our ignorance about disease mechanisms."

With new knowledge that has been gained about normal cells and tissues, medical science appears to be on the verge of a breakthrough in understanding of the inner mechanisms of heart disease, cancer, stroke, schizophrenia, arthritis, diabetes, and the other major diseases. Armed with such understanding, the future focus of medical research will be on the development of methods for intervening before the various disease processes even begin.

As suggested in a recent Presidential panel report, the ideal technology for comprehensive health care ultimately will consist of measures for the prevention of disease, and it will displace today's technological tours de force, which in the main are directed toward the termination of already established disease, or compensation for the loss of tissues and organs damaged by disease.

But what has all this to do with a less than three-years old legislative support agency, the Congressional Office of Technology Assessment (OTA)? The roots of OTA date back to the mid-1960's when it was becoming increasingly apparent to decision-makers in all sectors of the society that the advancing tides of technological changes were sweeping forward at such a pace that the full implications of such changes were not adequately being taken into account in the setting of public policy.

OTA, which came into being in November 1973 as a result of legislation enacted by Congress the previous year, was created to provide the Congress with a capability for fully assessing the diverse impacts, both direct and indirect, of changes in technology and technological applications. The information developed through the studies performed by OTA must be unbiased, timely, and based upon competent and authoritative examination of the full spectrum of possible effects—physical, biological, economic, social, and political.

Most of all, however, technology assessments performed for the Congress must identify legislative options and alternatives which will allow elected decision-makers to make informed judgments as to the role, if any, that public policy should play in influencing any given technological development or issue. Quite frequently, in the course of carrying out an assessment for the Congress, OTA's interactions with leaders in other branches of government and in the private sector will trigger complementary activity in those areas.

Health is one of the original priority assessment areas established at the outset of OTA's operations by the 12-member Congressional Board which sets policy for the Office. Senator Edward M. Kennedy, D.-Mass., who served as OTA's first Board Chairman during the 93rd Congress, has played an influential role in the development of the OTA health assessment program. Other major areas of OTA activity are Energy, Food, Materials, Oceans, National R&D Policies and Priorities, and Transportation. OTA's program teams in these fields frequently join forces in handling assessments which touch upon subjects of mutual concern.

One of the most interesting of OTA's health studies thus far—and one in which Lewis Thomas has provided assistance as a member of the project advisory panel—has addressed the potential role of technology assessment in the development of medical technology. In the course of exploring this question, we have worked closely with officials at the National Institutes of Health (N.I.H.) and have witnessed the parallel growth of inquiry into the same question carried out at the Executive Branch Level.

In June of this year, as the initial OTA report on the need to try to assess the impacts of emerging medical technologies was being readied for publication, Dr. Donald S. Fredrickson, Director of N.I.H., convened his own Advisory Committee for a two-day meeting on the subject of technology

EMILIO Q. DADDARIO, Director, Office of Technology Assessment, U.S. Congress, Washington, D.C.

assessment and its potential utility as a tool for setting policy in biomedical research. Among the participants in this meeting were myself and Dr. Frederick C. Robbins, Dean of the Case Western Reserve School of Medicine, who is chairman of OTA's Health Advisory Committee.

Given the influential role and responsibility of the Federal Government in providing support for scientific research, both basic and applied, as well as the increasing pressure for governmental involvement in the financing of health care delivery, the need for information about, and improved understanding of, the future impacts of biomedical technologies—their costs, their benefits, the ethical or moral questions they may raise—is essential at the public policy-making level.

If, as Lewis Thomas predicts, we are indeed at the threshold of a major shift from therapeutic to preventive emphasis in medicine, it is absolutely essential that our national policies be so informed as to make possible that transition without either undue acceleration or impedence. Many extremely difficult questions have been raised, not only in OTA's investigations but in those now being undertaken by the National Institutes in recognition of the need to take an early look at where its research programs may ultimately lead. While answers to many questions will not be simple—it will never be easy to back away from a technology that can save or prolong lives because of its expense. Yet it will be equally difficult to fund that technology with the knowledge that the money involved might save even more lives if put to a different purpose.

It is encouraging, however, to see that these questions are being asked and that men of good will from all sectors are willing to face up to them. At OTA, we see these questions rising from the Committees of the Congress and the elected representatives of the public. At N.I.H., we see these questions rising from within the medical profession, and particularly from within the biomedical research community itself. In both instances, we see advice being sought from diverse authorities, not just from involved government officials and scientists, but from a variety of disciplines and public-spirited citizens. Study panels include economists and sociologists, physicians in private practice as well as government research, consumer advocates, labor representatives, even theologians. It will not always suffice, of course, to simply ask the right questions, although a good question is often as important as a good answer. There is also no guarantee that satisfactory answers will necessarily follow questions properly put. Yet history has shown us that we generally can deal with the problems that we, as a society, recognize, and it

logically follows that the more quickly we recognize them the less entrenched and difficult they are to resolve.

OTA's initial activity in the health area, an assessment of questions related to the bioequivalence of chemically comparable prescription drug products, was spear-headed by another Yale Medical Dean, Dr. Robert W. Berliner, the current holder of that post. Dr. Berliner's contributions, along with those of the other members of the distinguished study panel which he headed, were particularly valuable since their report was the first to be presented by OTA to the Congress. Working against a tight deadline, dictated by Congressional hearing schedules, the Berliner panel assisted the OTA staff in getting off to an excellent start with the report, *Drug Bioequivalence*, which has gone through several reprintings and has constructive impact in the structuring of drug reimbursement policies for Medicare, Medicaid and other Federal health programs, and in the development of standards to assure bioequivalence.

The overall development of the OTA health assessment program is being designed to embrace a wide range of technologies which address a variety of medical objectives: diagnosis, disease prevention, therapy and rehabilitation, organization of services, and support of patients. These technologies take the form of both hardware (equipment and facilities) and software (methods and skills). The OTA staff has defined medical technology as "the set of techniques, drugs, equipment, and procedures used by health professionals in delivering clinical medical care to individuals and the organizational systems within which such care is delivered."

Following completion of the drug bioequivalence assessment, OTA identified five study areas pertinent to concerns of the Congress and deemed of high priority by an ad hoc panel of advisors concerned with many aspects of medical practice and health care delivery. These areas, in which applications of technology have a bearing upon the cost and quality of health services, are: medical technology development, drug utilization and effects, medical record-keeping and health information systems, technological involvement in medical malpractice, and the utilization of medical technologies in hospital outpatient departments.

Development of medical technologies—This assessment, originally requested by the Senate Committee on Labor and Public Welfare, addresses concerns that costly new medical technologies and procedures may be put into use without adequate justification or full understanding of their impacts. The assessment will consist of four parts: (1) a study of biomedical research and technology development, to

explore the feasibility of assessing the social impacts of medical technologies in formative stages; (2) an assessment of a specific technological innovation—the computerized axial tomography (CAT) scanner—recently introduced into use; (3) a study to determine whether new methods or mechanisms are needed to assure the effectiveness of new medical technologies, and (4) a study of means to weigh the projected costs of medical technologies against the value of their expected uses.

The Committee asked OTA to examine questions as to the effectiveness, appropriateness, cost, and risk to patients, of medical technologies, the development and application of which increasingly involve Federal funds. Typical of such questions is the choice of a proper balance between measures which may, in the long-term, preserve health and prevent illness for many, and those which may save lives and postpone death for a comparatively few persons seriously ill at present.

Drug utilization and adverse drug effects — Requested by the House Committee on Ways and Means, this assessment will examine major factors leading to the inappropriate use of perhaps the most pervasive of medical technologies—drugs. The study will focus on prescribing practices of physicians, labeling and instructions included in the packaging of drugs, and consumer responses to prescriptions and professional advice about the use of medication. The assessment also will devote special attention to adverse drug effects, their origin, their incidence, and prospective approaches for more effectively controlling them.

The objective of the assessment is to examine alternative actions or strategies for achieving safer, more effective, and more economical utilization of drugs and medication administered for therapeutic purposes. Included among the policy alternatives to be studied are peer review mechanisms for health professionals, drug utilization review systems, expanded dissemination of information about drug effects and proper drug usage, and improved monitoring systems for documenting the incidence of adverse drug reactions.

The assessment will concentrate on the use of prescription drugs, with lesser attention given to the role of drug products sold “over the counter,” without prescriptions. For purposes of this study, the abuse of alcohol and illegally obtained drugs will not be considered.

Hospital outpatient services —At the request of the Senate Committee on Finance, OTA is undertaking an

assessment of the various types of medical technologies employed in hospital outpatient departments, the utilization and costs of such technologies, and their effect on total costs and efficiency of health care delivery.

As an initial step, the OTA staff conducted a critical review to determine the adequacy of available information about the prevalence, utilization, and costs of outpatient department technologies, and to identify research needed to improve understanding of this phase of hospital care. Additionally, the staff examined possible methods for reducing costs or improving efficiency through dispersing or decentralizing certain hospital-based services.

Among the issues to be assessed are the ways that patterns of outpatient care are influenced by Federal health care financing programs. The study will seek to identify options, including possible changes in the reimbursement structures of Medicaid and Medicare, for making more efficient and effective use of medical technologies commonly employed in hospital outpatient departments.

Medical records and health information —This assessment, requested by the Senate Committee on Labor and Public Welfare, will examine technological advances in automated medical recordkeeping and health information systems and their potential for enhancing the quality of medical care.

The study will include consideration of information systems needed for health care research, planning, and management at various institutional and governmental levels.

The assessment will examine the need to safeguard the privacy of individuals, as well as other considerations and possible constraints which might effect the achievement of maximum benefits, and more efficient use, of medical and health recordkeeping systems and technologies.

Medical malpractice —This assessment will examine the extent to which applications of medical technology result in medical injuries and subsequent malpractice litigation and will seek to identify and analyze alternatives for reducing the incidence of such technology-related injuries. The project also will evaluate the cost and appropriateness of so-called “defensive” applications of medical technology, employed primarily in the interest of avoiding malpractice litigation. This project, is to be performed in response to a request from the House Committee on Ways and Means.

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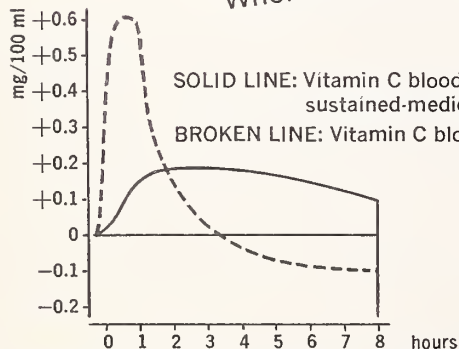


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¹ Riccitelli, M. L.: Vitamin C Therapy in Geriatric Practice, J. Amer. Geriatrics Soc. 20: 34, 1972.

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Reform in Drug Regulation Overdue

G. Frederick Roll

On April 30th of this year a panel of some of the nation's leading scientists sent a report to the President and to the Congress on biomedical research. In their report, this distinguished group took note of the extraordinarily difficult and complex role of the FDA, exposed as it is to a steady crossfire of criticism from forces including Congress, the media, industry, the academic science community and sometimes even the Administration itself. They acknowledged FDA's function as a regulatory agency protecting the public against hazard from new drugs, new food substitutes, additives and new devices. In conclusion, they observed: "Meanwhile, there is a different kind of hazard to public health, posed by the prolonged delays and great costs of developing new and potentially useful drugs which the FDA's own protective systems have imposed. In some respects, the agency has become a formidable roadblock . . . While it is clearly beyond our charge to propose ways for improvement of the FDA, the problem is there, and we are obliged to cite it in the context of this report."¹

The 1962 Drug Act (Kefauver-Harris Amendments) drastically changed the manner in which the FDA operates and regulates drugs. It also injected government into the R&D process itself. However, no committee of the Congress has carefully studied the effect of amendments and regulations on the benefit side of the risk/benefit equation, i.e. the discovery and development of new therapies. (Ironically, it was largely overlooked in the case of the recently adopted Medical Devices Act.) Sporadic hearings have been held, but mostly on narrow issues. When Congressman Paul Rogers (D Florida) recently held hearings on his new proposal, The Drug Safety Amendments of 1970, his opening statement made no mention of the need to develop new drugs. He justified his bill and the hearings as follows: ". . . the FDA has been the focus of increased public scrutiny, possibly more than any other federal regulatory agency," and ". . . it is time, certainly in my view, for the Congress to stop criticising and move to provide the FDA with sufficient authority to regulate properly and to carry out its responsibilities." Not one word about probing the effect of the 1962 Drug Act on innovation, and the effect that a slowdown in re-

search might have on the development of badly needed new drugs.

Table 1

ANNUAL APPROVAL OF NEW CHEMICAL ENTITIES 1950-1973 ³			
Year	NCE's*	Year	NCE's
1950	33	1962	30
1951	47	1963	13
1952	37	1964	25
1953	55	1965	23
1954	36	1966	18
1955	44	1967	23
1956	44	1968	7
1957	53	1969	12
1958	32	1970	17
1959	56	1971	17
1960	47	1972	11
1961	36	1973	18

*Excludes salts or esters of previously marketed drugs.

Over the last 15 years the regulation of drug development and use has become more and more stringent. The law and regulations, of course, were not conceived to encourage R&D. As Dr. J. Richard Crout, Director of the Bureau of Drugs of the FDA, said in December of last year: ". . . The issue isn't whether. . . regulation cuts down on innovation. Indeed it does. It must. There is hardly any way that regulation can stimulate innovation."²

The following are a few of the observable trends taking place:

1) There has been a decline in innovation as marked by a decline in the introduction of new chemical entities (NCE's). Some have observed that the decline in NCE's has been a worldwide phenomenon and thus conclude that regulation has not been the cause of the decline. However, Grabowski has recently observed that: "A consistent finding (of a number of recent studies) is that regulation has had a significant negative effect on the rate of innovation."³

2) Lasagna has recently pointed out that the decline in NCE's entering human investigation has another worrisome effect. He lists the following drugs and their use as examples of drugs whose value was only observed serendipitously after undergoing clinical trials for other purposes. He concludes that the fewer compounds studied in humans means less potential for innovation and discovery.⁴

Drug	Use or Entity Treated
phenytoin	anti-arrhythmic
lidocaine	anti-arrhythmic
probenecid	uricosuric
imipramine	anti-depressant

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acetazolamide	glaucoma, epilepsy
thiazides	diabetes insipidus; diabetes mellitus
diazepam	status epilepticus
propranolol	antihypertensive
vitamin D	hypoparathyroidism
co-trimoxazole	pneumocystis infections
estrogens, progestins	contraception
phenobarbital	epilepsy
iproniazid	melancholia
chlorpromazine	antischizophrenic
amphetamine	hyperkinesis
amantadine	anti-parkinsonian
metronidazole	rosacea

- 3) More NCE's are being sent abroad, at least for initial testing. This is happening at an accelerating rate (nearly 50% in 1974). There is an increasing fall-off in the number that are being returned to the U.S. for study; and those that are returned are taking longer to do so.⁵
- 4) While expenditures for R&D by U.S. firms in the U.S. are much greater than their expenditures for this activity overseas, the rate of R&D expenditures, through their foreign subsidiaries, is increasing twice as fast as domestic expenditures for the same purpose.⁶
- 5) Higher development costs and a lower rate of return on investment in R&D is causing a decrease in the number of R&D projects being undertaken by the drug industry.³
- 6) The increasing length of time for FDA clearance

of a new drug has shortened the period of patent protection, thus weakening the incentive to invest in R&D. Patents have a statutory life of 17 years. They are filed with the U.S. Patent Office before human testing begins. In most instances the patent is issued before a drug is approved by FDA. Below are listed (Table 2) the NCE's approved in 1975 in the U.S., showing the elapsed time between the filing of the IND to NDA approval, together with date of patent issue.⁷ It will be noted that on the basis of available data the average effective patent life is 10 years.

The present leadership of the FDA is the best qualified in years. The Commissioner, Alexander M. Schmidt, M.D., and J. Richard Crout, M.D., Director of the Bureau of Drugs, are both held in high esteem by their professional peers. Moreover, many of their top assistants and others appear to be well motivated and devoted public servants. Nevertheless, a common complaint is that the agency cannot attract and hold topflight scientific personnel in the line organization. Rufus E. Miles, Jr., who served as Assistant Secretary of Administration of HEW under six Secretaries from 1953 to 1965 expressed the problem this way in his book, *The Department of HEW*: "FDA has had an extraordinarily hard time in recruiting and holding able scientists and physicians. Good scientific work for the FDA does not seem to enhance an individual's reputation among the scientific community outside FDA; that community

Table 2
EFFECTIVE PATENT LIFE*

Product (Brand Name)	Manufacturer	Date of IND Submission	Date of NDA Approval	Elapsed Time		Patent Issue Date	Effective Patent Life
				IND Submission To NDA Approval			
Calcimar	Armour	5-29-67	1-3-75	91		NA	NA
Clonipin	Roche	6-7-63	6-4-75	144		1964	6
Cylert	Abbott	12-8-65	1-27-65	110		1967	9
Ditropan	Marion	5-8-69	7-16-75	74		1965	7
Dtic-Dome	Dome	3-16-66	5-27-75	110		NA	NA
Lotrimin	Delbay (Bayer, Ger.)	3-17-70	2-3-75	59		1972	14
Loxitane	Lederle	4-18-68	2-25-75	94		1970	12
Nebcin	Lilly	1-26-70	6-11-75	87		1972	13
Renoquid	Parke-Davis	7-20-66	9-12-75	110		1968	10
Sinemet	MSD	8-11-70	5-2-75	57		1973	15
Triazure	Parke-Davis	12-22-66	2-28-75	98		1969	11
						(Process Patent)	
Utibid	Warner-Lambert Chilcott	6-21-65	7-1-75	120		1966	8
Average				96 (mos)			10.5 (yrs)

*For all NCE's approved in 1975.

looks down on FDA science and some FDA scientists look down on themselves. It is a vicious circle from which it has so far been impossible to escape. Until that vicious circle is broken, FDA cannot become a first-rate scientific institution.” Dr. Crout confirmed this in recent testimony.² He said that he does not believe that the FDA will ever solve the problem of a wholly strong in-house staff, and that the recruitment of good scientific personnel is FDA’s major long term problem. One reason for this is obvious. A career devoted to poring over the tens of thousands of pages of data and forms which make up a New Drug Application provides no opportunity for scientific advancement. Another reason is the low morale which seems to persist in the agency, best described by Dr. Crout himself in public testimony on April 19, 1976: “You must picture the building as full of unhappy people, suddenly feeling their lives have been uprooted by moves from Washington to Crystal City, Virginia, and then to Rockville, Maryland. No carpets in the building. The place half painted. Walls being built and then torn down. I talked with physicians and pharmacologists about the NDA process at that time. They were clearly interested and concerned about the loss of documents, the chaos in applications, the fact that managerial assignments were confused. No one liked this. People felt they were on the hook for work assignments that actually had never been given to them. They felt they were operating like clerks. Nobody knew where anything was. There was an enormous documents room, where fights went on. There was absenteeism. There was open drunkenness by several employees that went on for several months. There was intimidation internally . . . In my first year at FDA in 1972-73, going to certain kinds of meetings was an extraordinarily peculiar kind of exercise. People—and I am talking about division directors and their staffs—engaged in a kind of behavior that invited insubordination. People tittering in corners, throwing spitballs—and I’m describing physicians. There were people who slouched in their chairs, did not respond to questions, and groaned with sweeping gestures. A kind of behavior I have not seen in any other organization as a grown man.”²

In the fall of 1974 Senator Kennedy, upon urging by the Nader-affiliated Health Research Group, held hearings to investigate charges that FDA had been guilty of arbitrarily transferring scientific personnel because of industry pressure, and of ignoring recommendations of medical officers as to approval and disapproval of new drugs. Secretary Caspar Weinberger, then head of HEW, appointed an outside panel (after Kennedy had vetoed its chairman at the urging of Anita Johnson of Nader’s HRG, and had

suggested a replacement as well of other possible panel members) to investigate the validity of the allegations. The panel was also charged to “review policies and procedures for the elimination of such deficiencies.” At first this was looked upon as good news indeed. In fact, in 1972 a group of noted academic scientists headed by the late Robert D. Dripps, M.D., then Vice-President of the University of Pennsylvania, had publicly urged that such an inquiry was badly needed. The review of the FDA procedures for clearing new drugs would obviously entail examining the scientific decisions FDA had made in the past, a task that would tax the best medical brains in the country. So, whom did Weinberger finally choose for the job? A seven member group made up of three lawyers, a retired physicist, a government toxicologist, a pharmacologist, and a medical school dean. At best, only three members of the panel (notably its former chairman) were remotely qualified for the job, and only he was experienced in clinical research.

After more than a year of monthly meetings, the Panel is still floundering around. A recent article in *The New England Journal of Medicine* characterized the Panel as follows: “The panelists for all their prestige and professional accomplishments, have turned out to be a bickering lot of hairsplitting metaphysicians, and if HEW Secretary David Mathews chooses to sweep them all out, it will be no loss to the Republic or drug safety and efficacy.”⁸ The growing dissension between the lawyer dominated panel members and its medical science members finally gave rise to the resignation of its chairman, Thomas C. Chalmers, M.D., Dean of Mt. Sinai School of Medicine. The Panel continues its sessions with Norman Dorsen, Professor of Law at N.Y.U. as Chairman. Now that Dr. Chalmers has resigned there is no one on the Panel who is expert in either the practice of medicine or the testing of drugs in humans. The final blow came last month during the Kennedy hearings, when in a bizarre move, the Senator interrupted Secretary Mathews’ testimony and pressured him into extending the life of the Panel until the end of March 1977, despite the fact that in letters to the Panel he had previously refused to do so. In a sense, this was a repudiation of the Commissioner. Two days later it was announced that Commissioner Schmidt was leaving his post by December.

It is coming to light that, in this setting, an FDA medical reviewing officer in 1968 frustrated a drug firm from going forward with a controlled study to determine whether chronic administration of aspirin in normal doses would prevent subsequent heart attacks and death in patients who had had myocardial

infarctions. Because of repeated demands for additional data, animal studies, and requests for submission of all the papers in the world literature on aspirin, the drug firm finally gave up.⁹ In 1974—six years later—the NIH initiated a \$16 million investigation of precisely the same effects of aspirin.¹⁰ Meanwhile, preliminary reports from overseas (where the drug is already being marketed by one German company in a dose form for this usage) suggest that the clinical studies already performed and those under way will support the hypothesis. If the information continues to be favorable, one can conclude that a single reviewing officer was responsible for delaying the use of aspirin to prevent fatal heart attacks in thousands of patients.

It is also coming to light that thousands of lives could have been saved if the beta blockers had been made available sooner. For example, in 1972 a prestigious group of academic medical experts in the field of hypertension testified as follows: "... it would appear that despite the efforts of FDA, the process of drug review continues to be bogged down. This seems to be the fault of lower echelon reviewers who are either unable or unwilling to make constructive decisions and who drag out the process of drug evaluation by making repeated demands for additional data, insisting upon inconsequential nitpicking details, and by a general approach of substituting new investigational demands for incisive decision-making."¹¹

The modern use of beta blockers for a variety of important new indications has been pioneered abroad, with the U.S. following ten years behind. Current studies are showing that they, too, can prevent heart attacks and sudden death, at an estimated saving of at least 10,000 lives per year in the U.S.^{12, 13, 14}

Undoubtedly some benefits have resulted from the 1962 Drug Act. Clinical testing was improved, with reliance placed on controlled trials instead of anecdotal evidence, and the investigational use of drugs was placed under tighter control. Also more attention is now being paid to record keeping and reporting of adverse reactions. But despite these benefits no one—the Congress, the President, the medical profession, the consumer advocates and the industry—is happy with our drug regulatory system.

What can be done about it? Unfortunately, in view of the current climate of public opinion affecting all of our institutions and the complexities of the problems, there are no easy pat answers. The incentive of FDA bureaucrats to speed up the approval process would be strengthened if the Congress would recognize by law that unnecessary delay can inflict just as much harm on the public as too much haste. It would also

be helpful if the decision making could be insulated as much as possible from inappropriate or improper pressures, whatever their source. The appointment of a top flight group of medical scientists with firmly established reputations and careers, whom the Commissioner could call on for policy guidance, would also be a step in the right direction.

FDA decision making should place greater reliance on advisory committees. Advisory committees, although used more frequently, are still called on at the discretion of the agency. The Medical Devices Act just adopted by Congress provides for mandatory outside advisory committees. If for medical devices, why not for drugs? Moreover, the composition of current FDA advisory committees is arbitrary and often inappropriate. Unreasonable conflict of interest restrictions exclude the most competent experts from such committees. These should be waived, except when a committee member is a shareholder in, or paid consultant to a company at the time its drug is being evaluated. Advisory committees should also include practicing physicians. For too long their role has been minimal in public policy decisions involving drugs.

It is clear that the development of new drugs is dependent on an innovative and productive research enterprise. It would surely help to adopt reforms which would free the research and development process from the heavy hand of bureaucracy as much as possible and vest more regulatory responsibility in outside expert committees.

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Dying in a System of “Good Care”: Case Report and Analysis

Martin G. Netsky, M.D.

The circumstances of the case to be presented are factual, but a particular institution is not implied. The report is intended to reveal what may commonly occur, as a basis for the analysis and conclusions.

An 80-year-old woman, my mother, became unable to manage her daily needs and was unwilling to be attended by those closest to her. She therefore decided to go to a nursing home. Mother's mind began to wander in those last months, but at lucid times she would ask, “Why does God let me live so long?” I usually turned away from the question; I simply did not know the answer. She made me promise she would not be allowed to linger under the devices of modern medicine. I agreed, but in the end I was unable to fulfill her wish.

In the nursing home my mother felt that she had lost her usefulness, was a burden to her children, and was not her “old self.” Repeated episodes of involuntary urination and defecation were extremely distressing to her, as well as to the staff of the nursing home, especially when the cleaning was delayed. A sudden alteration in her physical condition led to transfer to a hospital. There, she was at first partially conscious, but soon lapsed into coma. Extensive investigation and treatment failed to alter the coma, which persisted except for occasional lucid moments.

Upon arrival in the hospital emergency room, my mother entered into a course of diagnostic evaluation and treatment in an institution priding itself on good care. A course in medical ethics was offered at the associated medical school. At no time, however, could I determine who was responsible for her management. Many physicians entered and left the emergency room, but I was unable to identify which one decided to move her from the emergency room and to admit her to the hospital as an inpatient. Residents, interns, medical students, nurses, and aides moved around her in a swivel. Despite the fact that she was a “private” patient, she was assigned to an attending physician without anyone inquiring about my wishes or even informing me of the assignment. After the initial shock of the events disappeared, I was annoyed that I had not been asked what I wanted done, or whether I would approve of the physician selected. In the light

of later events, it probably did not matter. Most doctors in the institution were trapped by the system.

What happened was a nightmare of depersonalized institutionalization, of rote management presumably related to science, and based on a team approach of subdivision of work. The nurses gave by far the best care. My mother's unconscious body was cleaned and bathed regularly, but no regularly identifiable person performed these functions. Different nurses wandered in and out of my mother's room each hour, each shift, each day, calling for additional help from nameless others over a two-way radio. They rarely introduced themselves to me. They were trained as part of a team “covering the floor” rather than aiding a sick human being.

A few months before, when undergoing minor surgery in the same hospital, I had noted similar nameless packs wandering into my room—residents, interns, registered nurses, licensed practical nurses, student nurses, nurse's aides, takers of blood pressures, takers of temperatures, cleaners of the floor, cleaners of the woodwork above the floor, orderlies, technicians, and indeed almost everyone but the surgeon. Most elements of this impersonal horde never identified themselves. It was as if each was obligated to perform a set task in relation to tended bodies in various rooms. The teamwork and subdivision of labor presumably made each person more efficient at his work, but the depersonalization chilled me.

The physicians began the routine ministrations to the patient, my mother. The resident told the intern and the medical student what tests to order, initiated the giving of fluids, oxygen, antibiotics, set the frequency of recordings of blood pressure, pulse, respiration, temperature, and the insertion of tubes. From my knowledge of the system I supposed that the resident was consulting with the attending physician, but my assumption never was verified. My inquiries resulted in vague reassurances, and I was reluctant to press the issue.

Occasionally, the initials of the attending physician appeared on the progress notes, which I was privy to read, but there was no progress. I was a regular visitor, but I did not see this doctor for many days. He was “on rounds,” in conference, lecturing, out-of-town, or simply not available. The resident came to his “end of service,” and a fresh, unversed man became visible. I tried again to see the attending physician and asked the new resident for assistance. He had

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no knowledge of how to locate the attending physician, nor the method of obtaining an audience. I called the medical secretary, saying that I wished to talk to the physician-in-charge. The peremptory answer was, "Is this an emergency?" Possibly she was shocked when I replied, "Yes, my mother is dying." Clearly, the secretary saw her function as a shield against anxious relatives.

When the meeting between me and the attending physician was finally achieved, I explained what my mother had said when lucid: she and her closest relatives, including my brother, did not want unnecessary prolongation of the agony of dying. We would prefer, for example, that oxygen and antibiotics not be given. The attending physician listened sympathetically, understood fully, and agreed completely; but *nothing changed*. He who should have been in control of the system was dominated by it! Laboratory studies of blood and urine continued to be performed, fluids were given, oxygen was bubbled in, antibiotics were administered; and days went by but seemed to be years. The patient was seen occasionally by large groups of physicians making rounds, presumably learning the art of practicing medicine properly.

I began wondering who looked at the accumulating mass of data. The nurses recorded their detailed observations of vital functions and behavior, but did anyone except the nurses see the comments? The chart was enlarged regularly with the "progress notes." These hastily scrawled writings always dealt with laboratory data, never about the feelings of the patient or her family, and certainly never with the question, is this effort necessary or wanted? Yellow slips of laboratory data and reports of special procedures continuously added to the thickness of the chart. My mother's inert body was regularly weighed, but for what purpose I did not know, except that it was part of standard management for medical patients, and gave a member of the team another routine duty to perform. Life was being preserved, but little thought given to the means or the purpose.

One report stated that occult blood had been found in the stool. Someone responded by writing in the chart that, in view of this finding, sigmoidoscopic examination and a barium enema were indicated. I suggested to the author that his conditioned reflexive act was not warranted in the case of an unconscious 80-year-old woman who wanted to die gracefully. If a cancer of the bowel were found, would he subject her to major surgery? He admitted he would not. Then why make the suggestion? "That's what I have been taught," was his answer. The laboratory studies continued to grow, and the records now were massive.

I managed another conference with the attending physician. His response was to ask for a consultant to

see the patient. The new person stated on the chart, but not to me, that the care being given was the best and the "regimen" should continue. The residents reacted similarly, regularly calling for other physicians—"consultants." The usual function of the consultant is to offer ideas of diagnosis or treatment not previously considered, not in the domain of expertise of the attending physician. Most consultants suggested additional studies in the sphere of their own competence. I did not want more studies, preferring compassionate care, and I refused the services of one consultant. Another offered *me* the opportunity to be the physician for my mother by *my* deciding whether she should have burr holes placed to look for subdural hemorrhage. I decided he was treating me rather than her, and that he should make the decision, allowing me to approve or disapprove.

At this juncture, I considered removing Mother from the hospital. The nursing home would not take her. What about another hospital in town—would they offer more humane and individually responsible treatment? Being uncertain, I decided to wait until further inquiry revealed whether the present treatment would be repeated elsewhere. I even contemplated bringing her home, but decided, perhaps foolishly, that a hospital was more appropriate and that the end might soon come.

Agonizing time went by. We waited for the merciful end, but experienced no mercy from the physicians treating her. Each did his routine job of saving life when it was almost not present. A formerly vivacious and attractive person now existed only as a human body with a beating heart but little other evidence of humanness. Suddenly, the action of the heart became irregular, clots were formed, some entering the lungs, and then even the mechanics of life ceased.

The enormous monetary cost of this case was paid fully by various agencies. The time, energy, and personnel expended were incalculable, the prolonged anguish of the family inexpressible. Lives of starving children or of socially deprived people could have been saved with less expenditure, but the system, confronted by the body within its halls, was put inexorably in motion. The people trapped by this routine performed their actions because they had been taught that life must be saved at all costs and at all times. They sincerely acted as if they offered good care. They paid no heed, however, to the wishes of the living, nor of the almost dead, but only to their own presumptions. It struck me that similar events were occurring in almost any "teaching" hospital in the United States.

After my mother's death persistent questions arose in my mind about saving life, and about what constitutes proper care of those patients who are not salvageable. If the care offered by a "teaching" hospital

produces undesirable results, what is it that is wrong? Legalities and religiosities aside, can both compassion and clear assessment of the particular case be applied? Why do those dedicated to giving so-called good care not accept differences in effort made to prolong a life? Some physicians clearly do pay attention, but why do so many not consider the differences, and the desires of each individual? Why is there no presently acceptable way of saying, "This person is very old and has had a long full life, and now it is impossible to make her well again. I will therefore do nothing to discomfort, demean, depersonalize, deform, or deter the natural process of dying serenely"? The treatment given my mother would have been appropriate for a young person with years ahead of potential value to self, family, and society, but the system did not alter its methods, nor recognize the difference. . . .

Later, at a time of less emotion, a different question arose. How had this senseless fight against the process of dying developed? As a medical educator, first as a clinician, and then as a pathologist, I tried to inculcate in my students a respect for the living, the dying, and the dead. Concern for the healable patient is not the issue here. An ethical concern for the preservation of life at all cost has been inculcated in us. Even when death was certain, we would vigorously treat persons with severe burns covering 95 percent of the body surface. For the patient in our institution no effort, no cost was too great. The concept was that life must always be preserved. Death, then, was an affront to the physician, a challenge to his wish for omnipotence. We paid lip service to "public health and preventive medicine," but few medical schools, hospitals, or physicians made efforts to help the millions of people outside their halls who died for lack of food or love. . . .

It would be simplistic to say that enforcement of an ethical principle is the entire answer. Medical education is a dehumanizing process, not intentionally, but effectively nonetheless. Anatomy often begins with dissection of a dead body. Western culture promotes fear or dislike of death. Some students must harden their feelings to deal with the cadaver, and to overcome this cultural bias. The remainder of basic science largely has become "molecular biology," so that students know much about mitochondria, and the effects of cyclic AMP, but receive little information about the personal problems of human beings. Courses in medical ethics are given, and some teachers try to view persons as a whole, but students recognize that the intellectual excitement lies elsewhere in the minds of most members of the faculty. They meet few physicians who model primary concern for the overall care and well-being of the patient, but daily see those with an overriding concern for knowledge in fragments of differing importance.

Pathology, a field not related directly to the patient, makes its contribution to the dehumanizing process. Disease is the primary interest rather than the reaction of a person to illness. Indeed, the definition of *disease* cited in American medical dictionaries emphasizes the impersonal or mechanical aspects: "A definite morbid process having a characteristic train of symptoms, it may affect the whole body or any of its parts, and its etiology, pathology and prognosis may be known or unknown" (*Dorland's Illustrated Medical Dictionary*, 24th Edition).

By contrast, in *Butterworth's Medical Dictionary* (formerly the *British Medical Dictionary*) *disease* is defined in terms of a person: "In general, a departure from the normal state of health. More specifically, a disease is the sum total of the reactions, physical and mental, made by a *person* to a noxious agent . . . a metabolic disorder . . . a food deficiency. . . . Since a particular agent tends to produce a pathologic and clinical picture peculiar to itself, although modified by individual variations in different *patients*, a mental concept of the average reactions or a composite picture can be formed which, for the convenience of description, is called a particular disease or clinical entity. *But a disease has no separate existence apart from a patient, and the only entity is the patient.*" (The italics are mine.) . . .

Even the teaching of clinical medicine is too often similarly dehumanizing. The "good case" is more important than the "crock," a derogatory term for a person whose problems are not solved by a scientifically trained physician. Clinical rounds commonly are exercises characterised by large groups of doctors, nurses, social workers, and dietitians gathering around the bed of the patient. The discussions concern laboratory data and making the diagnosis rather than the patient himself. Demonstrations reveal physical signs or operative incisions, not the hopes and fears of the ill person.

The training of the physician minimizes emotional involvement with the patient and his family, in part to prevent these considerations from interfering with decisions, and in part because too great an emotional concern may be self-destructive. As a result, conversation with other physicians is likely to be about the disease rather than the patient: "The ulcer in the second bed is getting better." The student reads textbooks describing symptoms and signs as if they occurred in a disease, not in a sick person: "weakness, atrophy, and Babinski signs occur in amyotrophic lateral sclerosis" rather than in a human being ill with this disease. Dictionary definitions, conferences, recording of notes, discussions, and use of language all serve to enlarge interest in the process of disease, and to decrease concern for the person who is ill. None of these features alone is bad, but

their cumulative effect lessens the importance of the sick human being. . . .

The practicing physician faces many other difficulties in dealing with death. Often he has not participated with his teachers in the consideration of dying patients. He may fear or resent the death of a patient, finding it an affront to his strenuous efforts. He may salve his conscience by escalating orders for diagnostic procedures or treatment. At the same time, doctors and nurses tend to visit a dying patient less often, although the person facing death may need human contact even more. Dying patients undergo "social death";¹ relatives, friends, and medical personnel view the patient as not existing. The physician has limited time. He enjoys visits to patients who can be cured, and allots shorter periods to the dying person.

To these factors has been added the impact of courts of law and the legal profession, as well as the personal and financial burden of suits for malpractice. In practicing medicine in such a way as to avoid lawsuits, the physician may damage the patient, feeling compelled to request excessive numbers of tests, many not innocuous, and to order procedures to maintain life beyond any usefulness. Humane medicine deals with *this* patient and *his* problems. The law works by rule. For a physician, every patient should be exceptional; past experience offers a guide to action but is not necessarily a determinant. A lawyer views all cases by the same standards, and precedent is important. But should the practice of medicine be conducted for the patient, or for the lawyer? Laws can be changed. Unnecessary suffering or harmful drastic measures should not be legal: excesses of this sort should be exposed, fought, and eliminated.

What is needed is the rare quality of good judgment. Benefits and risks should be weighed for each person, and decisions made by careful reasoning with-

in the framework of enlightened law rather than by rote or system. The feelings of the family should be carefully weighed, and the opinions of other physicians or non-physicians sought, but in the end, a decision should be made through the merciful judgment of one properly trained human being who has full responsibility. . . .

These paragraphs were written long after the actual events. When in the midst of the incident, I was disturbed but, in general, accepted what was done. I was as much a part of the system as the physicians who treated my mother. Recently a personal memoir by Lois Wheeler Snow² concerning the death of her husband revealed further evidence that insensitivity to the personal needs of the patient and the family is related to our training. A private Swiss clinic treated Edgar Snow and his wife; their major concern was with the disease. Open discussion with the family was actively resisted. The medical team of another culture managed the individual problems of the patient and the family far better. When the Chinese came, they shared all information: doctors, nurses, the patient, and the family discussed problems openly. Medical personnel were freely available to the family. The patient received companionship whenever he wanted it. Emphasis was on the person, and the family, as well as on the incurable illness. "There is yet a limit to technology; there is none to humanity, beyond our own making."²

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The Polygamous State of Mental Health

Clifford W. Beers Memorial Lecture

Yale University, February 5, 1976

Reginald S. Lourie, M.D.

Introduction by Albert J. Solnit, M.D.

It is a privilege and a pleasure to introduce the second Clifford Beers Memorial Lecture. First let me sketch in the background for this memorial lecture, one that has national significance as well as its importance to Yale.

As quoted in Dr. Willa Abelson's scholarly account of the Clifford Beers Guidance Clinic on the occasion of its 50th birthday in 1963,

The dramatic beginnings of the Mental Hygiene movement took place just a short walk from the present site of the clinic on Temple Street in New Haven now at 1 State Street. They were led by the young Yale graduate, Clifford Beers. Beers' personal knowledge of mental illness, which he described in his book, *A Mind That Found Itself*, and his experiences in several Connecticut psychiatric hospitals (then referred to as insane asylums) had generated his determination to organize a movement which would work for the amelioration of conditions within mental institutions, the prevention of mental illness and the education of the public regarding its nature.

Believing in the prevention and cure of mental illness, against the odds of adverse opinion and public antipathy, Beers forged the first link in his dream of a national mental hygiene movement on May 6, 1908, when the first meeting of the Connecticut Society for Mental Hygiene was called.

The purpose of this Clifford Whittingham Beers Memorial Lecture is to review the developmental state of the field of mental health from its conception to its maturity. My particular emphasis is on the fact that mental health cannot live alone. It cannot be separated from health, education, law, and the social and cultural forces it lives with. There have been many healthy and productive liaisons, but also some poor marriages and intrafamilial struggles. However, we now even hear voices in favor of mental health returning to a more monogamous state and even those which point to the marital constrictions of the Koran, namely, that a family should include only as many wives as the husband can support. I decided to bypass the questions in which of its marriages mental health is the bride and when it is the groom; where

mental health is only dancing with others, and which of its offspring are illegitimate. In the positive spirit of Clifford Beers, it seemed best to look ahead, to discuss where the most promising marriages should be going, and what opportunities are yet to be explored.

When the field of mental hygiene sprang alive from the head of Clifford Beers, it had a lot of growing to do, unlike Athena who sprang from the head of Zeus fully grown. Although its prenatal period was attended chiefly by psychiatrists and psychologists (Adolph Meyer gave it its name of Mental Hygiene), its birth at 149 Elm Street here in New Haven was attended by 14 men and women, not only from Beers' immediate family, but also from the disciplines to which it was then promised in marriage. Those attending included representatives of the law, education, the clergy, the community, consumers, social work, and medicine. This afternoon let us have a short visit with a few of the current issues involved in some of these more or less formal marriages.

I shall start with mental health and the law, since here at Yale there has been some of the most active communal interaction between law and mental health. As the law slowly began to listen to the mental health professionals, beginning with the field of juvenile justice in 1909 when mental hygiene was only one year old, the law became increasingly dependent on its new-found partners. As David Bazelon expressed it,¹ "the law followed the information in the mental health field." Law began to love, honor, and obey. It even stopped calling some of its mental health partners "alienists," with all that this title implied in the public eye. But those happy days are over. The roles are reversed. In the vanguard of the feminist movement, Justice, symbolized on the steps of the Supreme Court as the blindfolded woman holding balanced scales, began to react to criticism of its decisions about mental competence. One of the fingers of the hand not holding the scales began to point to the deficiencies of the mental health field which promised more than it could deliver. This crisis, not unusual in any marriage, was loudly reacted to in some legal corners by cries of "divorce." Taking the situation into her own hands, Justice made a number of fundamental decisions about how mental health should function. The dependency picture is reversed, and it probably will stay that way. At this point the cooler heads among the thinkers on both sides of this

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partnership acknowledge that obviously neither one can live without the other. In the mental health field we have begun to reassess what we really do and do not know, and where the gray areas are. The beginnings of sharing this with the leading thinkers in the law are coming from contributions being made here at Yale, such as *Beyond the Best Interests of the Child*.²

The ingredients necessary to keep this momentum going are people, including those who can integrate the best interests of the law with the best interests of mental health. The occupational hazard is a divergent squint resulting from looking in opposite directions, at the same time, with traditions vs. new information. The health of this marriage seems to have a sounder future than a past. With a proliferation of societies, study groups, seminars, and academic centers concerned with these areas, law and psychiatry can live together and produce healthy children such as the outstanding manuals by Joseph Goldstein and Jay Katz.³

As an infant, the field of mental hygiene made its first steps into the community. In its early years it shared with psychoanalysis the lack of immediate acceptance by the inclusion into the existing health system. There were a few exceptions. For example, the records indicate that the Department of Psychiatry at Yale had some of its origins in the work of the Connecticut Society for Mental Hygiene, which Clifford Beers originated. For the most part the new being was taken in by the family of social agencies. As mental hygiene developed out in the community, it provided the stimulus and wherewithal for the development of community child guidance clinics and services for the "shell-shocked" veterans of World War I. However, it was not until its acceptance by the armed services in World War II that the mental health team, the unique family cooperative which community mental hygiene gave birth to, was recognized for its capacity to expand the services formerly provided chiefly by the psychiatrist. Once accepted, the mental health team concept became one of the prototypes of a wide range of nonmedical health services. It became the heart of the community mental health center programs, the mental health darlings of the 1960s; but it also became the corps which now provides 85 percent of all health care in this country.

The bridge which was built between the mental health services and the community provided one of the first opportunities for more participation by the lay public than serving on boards or raising money. It is not generally known that Clifford Beers was an early model of the consumer turned paraprofessional. For three years he treated troubled people in

consultation with professional colleagues at the Connecticut Society of Mental Hygiene. He had the advantage of direct hospital experience, and all the disadvantages that it entailed. He became the prototype of consumer-participant in modern-day terms. This model has only recently been found valuable, notably in the drug abuse field where ex-addicts appear to be some of the most effective therapists. Beers was far ahead of his time: it took more than 60 years for his model to be followed. The Navy is now recruiting ex-alcoholics, and some ex-prisoners are turning out to make the best probation officers.

When the consumer-participation model emerged in the Great Society programs in the 1960s, a number of the community-based mental health programs, particularly those in our inner cities, went through a new experience, very different from the traditional volunteer-consumer role.

In some community clinics the new model was defined as participation in professional-program decision-making. In some places this was accomplished or accompanied by tactics of confrontation. This phase has passed, but a number of interesting and useful insights have emerged. The relevance of mental health concepts and methods to the problems of poverty and social injustice was severely questioned, which in turn forced mental health to reexamine itself. There was the now familiar attack on the medical model as applied to mental health; the sickness model was said to disregard the positive aspects not only of people, but also of families and neighborhoods and cultures.

These confrontational tactics became contagious. In professional schools, our medical, social work, psychology, and law students picked up these themes; and some of our academic colleagues, challenged by their students, found themselves facing dead-ends when the validity of current concepts was challenged. They became like the landlord in the Great Depression arguing for hours with his tenants who were on a rent strike. Finally, the landlord said, "O.K., I'll lower the rent, I'll give you more heat, I'll collect the garbage every day, but I can't free Tom Mooney" (or, in modern-day terms, Eldridge Cleaver). At the same time a number of our colleagues became activists for social change and tried to free Tom Mooney.

The negative experiences growing out of the consumer-participation phase include the eye-opening observation, distressing to some, that when the downtrodden and disadvantaged are given the position of power, they deal with it in ways very similar to those of the decision-makers whose places they took. It brings to mind the title of one of Maurice

Levine's articles, "Oedipus, Abel and Cain and the Geographic Full-Time System."⁴ What we have learned from this phase is that in terms of professional decisions we must function not like the General Assembly of the United Nations but more like the Security Council where everyone has a vote, but those who developed the concepts have an overriding veto. But overall, after this forced marriage we can never be the same. We had been operating on the basis of an earlier Lord Chesterfield's advice about marriage: beforehand, keep your eyes open twice as wide, and after marriage keep them halfclosed. It has opened our eyes to areas where they previously were half-closed, especially in regard to the problems of minorities. For example, when we examine what we already know about personality development, we can better understand how one of the greatest problems faced by minorities, racism, begins. We know of its beginnings in the presence of separation anxiety, when fears of different color of hair can originate, especially when reinforced by individual and environmental experience. When we ask when the developing child asks himself and others whether black or white or red or yellow are good or bad, clean or dirty, beautiful or ugly, we find that it is usually between the second and fourth years of life. Can we accept the challenge to apply preventive and corrective approaches to where these roots of racism lie?

The mental health field has had a number of effective proponents with considerable persuasive powers, and Clifford Beers was certainly a great prototype. However, he and those he inspired oversold one of the cornerstones of the mental hygiene movement, the prevention of mental illness, a concept implied in its name. Unfortunately, the field was not yet ready with the information that could be applied preventively. The failure to produce on this stated objective of mental hygiene led to massive discouragement, particularly about primary prevention, a discouragement which has begun to lift only recently. This failure was one factor which led to the change of name from mental hygiene to mental health.

The mental health liaison in which prevention has the greatest potential but in which it is far from realization is in education. Yet education was one of the first organized disciplines to bring the mental health teams into its everyday functioning. However, these teams were immediately confronted by such overwhelming numbers of problems, that ever since they have been, as some of our involved colleagues describe it, so busy with fighting fires that they had no time for fire prevention. Still, some educational authorities who were members of the Joint

Commission on the Mental Health of Children insisted that the schools are not and should not be in the mental health business. However, when they took a closer look, they found that they had built into their own systems psychologists, social workers, counselors, and consulting psychiatrists some of whom have fortunately begun to think in preventive terms.

There is a slow revolution taking place in education. It grows out of the ferment and dissatisfaction stimulated by the failures of current methods of teaching, particularly for and with children from our inner cities. The real failure is in education not applying in preventive approaches what it has learned together with its partner, mental health. The handicaps in learning, major and minor, which children bring to the first grade could be identified before the children come to elementary school. The first school experience could then be structured to deal with these most fundamental problems. From this point of view, we can also fault the mental health field. When a prime opportunity became available to developmental health screening methods in the federally mandated Episodic Periodic Screening Diagnostic and Treatment program, mental health was not able to present a useful approach which would identify psychological, social, and other pertinent areas of individual vulnerabilities or to provide a basis for writing educational prescriptions for them. Education, too, has much to learn to be able to use such prescriptions. There would have to be concomitant changes in the curriculum of the schools of education, not only in the proliferating special educational training programs, which deal with the failures after they have been produced. This is a challenge for our "marriage counselors" or planners who deal with whole fields. They should emphasize working with children where they are. The programs should not be based only on teaching physical and personality distortions; they also should consider how the child sees the world and his or her own needs. For example, an inner-city first grader was taken to the National Gallery of Art. When she was shown the renaissance paintings of the Holy Mother and Child, she said, "The baby has no clothes, the mother has no shoes. Why did they paint their pictures?"

There are other things about teaching and learning which education must develop. For example, it does not yet know how to keep intact the precocious mathematical ability some children bring to school, only to lose it when formal teaching of arithmetic begins.

It has become a cliché that our greatest hope for effective primary prevention is at the beginnings of life and in our ability to identify individual areas of risk

and vulnerability. Yet, if there is one single most important finding in the work of the Joint Commission on the Mental Health of Children,⁵ it is that there has been relative neglect of the problems of our children's first three years. In the early days, Dr. Arnold Gesell, who put a lasting spotlight on what happens in the early years, worked in the clinic operated by the Connecticut Society for Mental Hygiene. There is no indication that his interests in the first years of life were translated into his ventures into the clinical field. We can suspect that then as now, it was difficult for many of even our pediatric colleagues to accept the concept that a baby under one year of age can have an emotional problem. Fortunately for babies and their families, a body of information about the first years of life has been accumulating and is being applied in clinical programs. Subspecialties not only of infant psychiatry but also of infant education are evolving. There are now available annotated patterns of psychopathology unique to the first years of life. As for those who still are disbelievers, we can remind them of Sigmund Freud's response when he was bitterly attacked after he had presented his findings on infantile sexuality at a medical meeting. He said, "Gentlemen, I wish it weren't so. It has complicated my life greatly. But the facts are . . ."⁶

As a confirmed matchmaker, I am looking ahead to a new liaison for mental health with obstetrics, which is developing ingenious methods of intervening in the pregnant uterus. The fields of child psychiatry and child psychology are not yet ready to be directly involved in the psychological life of the foetus, but there is evidence that we can look forward to the evolution of a new type of behavioral embryology with which we shall eventually be concerned. For example, in his study of "The Foetus as a Personality," Liley points out that some malnourishment of the foetus can result from a form of foetal anorexia—refusal to drink amniotic fluid.⁷ If saccharin is put in the amniotic fluid, some foetuses drink more, but some stop drinking altogether. Individual differences in the amount of aggressive energy and in patterns of defense in response to stress are already evident at birth. There is increasing evidence that more detailed knowledge of the prenatal period will help us understand the psychosomatic problems of later life. An organ's or organ system's responses to stress show characteristic patterns which are imprinted during the period of its development such as when its oxygen supply is threatened. This "basic" defensive response, it has been hypothesized, will be available later in life in response to stress.

The field of child mental health does have the capacity to develop programs based on the available information about the roots of the problems which

later confront individuals, families, and societies. Overlapping examples of such information include:

1. Just as the brain requires appropriate nutritional elements for its proper growth, it requires psychological experience and environmental stimulation for its functional and even for its structural development. Experience molds structure.

- (a) Retinal organization in early development fails to survive disuse. Abnormal inputs during the early years of life permanently modify the receptive fields and synaptic properties of the brain.

- (b) External stimulation and environmental complexity are said to influence the internal, anatomical maturational processes by increasing the richness of synaptic junctions, favoring progressive complex arborization of dendrites in the first few months, increasing the degree of vascularization, and furthering the process of myelination.

- (c) Deprivation of patterned sensory input produces cell loss in mammalian brains.

2. The capacity of the human brain to integrate and organize information probably begins before birth, but its most important later development takes place in the first year of life. When the synthetic functions of the mind are not encouraged, they can develop with limitations which lead to difficulty in mastering more than simple tasks. This also has implications for an individual's ability to respond to stress in organized vs. disorganized patterns.

- (a) In the first year of life, there is no connection between the senses until this integration is learned. This is one of a range of fundamental learning experiences which are organizers of both mental and behavioral patterns and require experience and reinforcement for appropriate development.

- (b) Early, severe, prolonged malnutrition has been demonstrated to result in reducing the number of cells in the cerebellum, one of the coordinating centers of the brain. At the same time, the studies of Levine,⁸ Frankova,⁹ Levitsky and Barnes,¹⁰ and Cravioto¹¹ indicate that replacement of nutritional requirements is not enough alone to allow recovery of lost function. The accompanying introduction of other stimuli in the environment, however, can ameliorate some of the deficiencies.

- (c) A depriving environment—regardless of whether the deprivation is of nutrition or stimulation—results in disturbances in the capacity to synthesize, beginning with the curtailment of DNA and protein synthesis. Winick¹² demonstrated that DNA synthesis is

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impaired because of lack of substrate (nucleotides) and because of reduced activity of enzymes necessary to accomplish synthesis. We do not yet know the more precise mechanisms underlying later failures in integration such as in the children presenting a range of perceptual-motor disorders. But it is known that feedback from the motor system is necessary for both sensory and higher mental functions. Malnutrition and lack of experience in synthesizing impair motor functions.

(d) Once established, a lessened capacity to synthesize can be seen clinically as a component in an individual's tolerance for anxiety. In turn, the poor tolerance for anxiety leads to less adequate solutions and even to perpetuation of developmental stages which involve fears, such as the expectable, phase-appropriate concerns about body integrity, separation and loss.

3. There are critical (also called sensitive or optimal) periods for the development of specific functions. These have major implications for cognitive development and the development of relationships and environmental expectations.

(a) The human brain, in contrast to that of the other mammals, has the capacity to recover function even after the critical period of developmental readiness has passed. However, if the critical period is allowed to pass, there usually is less than optimal development of the functions involved.

(b) For reasons that are not yet completely understood, early learning, including learned emotions and attitudes, is peculiarly resistant to change. Thus, if in early life a child has no trust in his needs being met, he often will carry a lack of trust into his later relationships and reactions to authority. (Some cultures deliberately encourage this trait; when one is surrounded by enemies, a suspicious nature is useful.) Similarly, die-hard loyalties to traditional practices are also established in early life and will later manifest themselves by resistances to the introduction of new technologies, family planning, diet, etc. Such lack of flexibility is established in some individuals even before 3 years of age.

But since we have this knowledge, what is in the way of our applying it? It becomes evident that even our strongest marriage—that with pediatrics—is not enough. Even the current polygamous state of mental health is still not enough. It has to make more marriages. The Joint Commission found that although at least 15 billion dollars are spent yearly on U.S. programs related to children and families, the money is allocated to programs that are separate from each other. The end result is a service system that is

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overlapping, even duplicating and competitive, fragmented, and less than responsive to many individual needs. Millions of children fall between these cracks. Every governmental agency has a program involving children—not only Health, Education and Welfare, with whom mental health lives more or less comfortably; there are the Departments of Commerce, Interior, Agriculture, Labor Transportation, Justice, Housing—all except the Bureau of Mines, and we didn't look too closely there.

The basic problem involved is power, much of it measured by the size of the departmental budget. One concerned bureaucrat described the next step after the budget is corralled, which is to build a barbed wire fence around one's budget and man it with armed guards to prevent outside raids. On the broader scene, the same problem exists. In the United Nations we find similar overlapping and fragmentation among UNESCO, WHO, UNICEF, FAO, ILO and a dozen or more smaller social welfare-related programs.

Mental Health has not been in a position to woo these unrelated agencies in our own government, and they rarely have asked us to have dates with them. The Joint Commission opted for a marriage broker with clout, who could say to the wide array of our agencies that they must live and work together for the overall benefit of the same children and youth with whom they are all concerned. The needed clout could only come from the very top level, the White House. The Administration listened, but compromised and established the Office of Child Development which was given the mission of coordination of children's services. There were great hopes then because for the first time there was a voice for children directly in the Office of the Secretary of HEW.

Unfortunately, O.C.D. was also given a range of granting programs, some inherited from the Children's Bureau, the remains of which it absorbed. It also acquired, as a political expedient, Head Start and Child Center programs. When we presented the Joint Commission findings to then HEW Secretary Elliott Richardson and his agency heads, he warned O.C.D. that it either had to give up being a granting agency and continue to have the Secretary's ear or go back down in the hierarchy to where the other granting agencies functioned. O.C.D. opted to keep the money, and it is now back five levels down where the Children's Bureau had been. Thus, we have to make a fresh start.

As we look ahead, if our marriage analogy hasn't worn too thin, we can envisage future liaisons in which mental health must be the dependent partner, rather than the many liaisons in which there is dependency on support from mental health. Even as he wrote "Anatomy is Destiny," Freud is reported to

have pointed out that the ultimate answers to the personal and social problems with which he dealt would come from the laboratory.

Man began as a creature of nature. In terms of the life of the earth, it is estimated that man is only the equivalent of 6 years of age. As 6-year-olds we still have a tremendous amount to learn about the forces and still hidden secrets of nature. We are trying to make nature the agent of man, but are far from controlling nature.

In the neurosciences many of our colleagues have devoted themselves to finding the microscopic neurophysiological and neurochemical mechanisms underlying the functioning of the mind, and are beginning to throw light on nature's secrets. Some of these basic scientists are working in settings where there already is a partnership with clinicians. The bridges that have developed connect such clinical concerns as the studies of schizophrenia and the affective disorders with molecular genetics and neuropsychopharmacology. A few neurophysiologists (such as Paul McLean and Fred Worden) have also traveled in close touch with theories of psychological functioning and are attempting to make as yet crude connections between the microscopic patterns and observable mental patterns.

In the early days of psychoanalysis there was an enthusiastic rush to translate the newly discovered mental mechanisms into explanations of basic physiological functions. These premature approaches quickly were found flawed and such attempts fell into disrepute. Actually there is validity in this conception, if it is properly applied. For example, the psychological defenses are no different from the defenses of the body's tissue and organs; only in the past we gave them different names. Interestingly, even patterns of body system functioning are beginning to be described in terms similar to those prevalent in the psychological sciences. For instance, some immunologists are talking in terms of depression, immobilization, symbiosis, and aggression in immune systems.

As a retreaded genetecist and cytologist, I suggest that the basic defenses of the body and mind are already established in the cell. When a cell is placed under stress, it has essentially four basic defenses. It can die, the ultimate in retreat and withdrawal. It can change form, especially to more primitive forms, not unlike regression and a return to primary process. It can proliferate, with resemblance to acting out. It can wall itself off, in many ways similar to the process of repression. A question still to be explored is how these defenses of the cell are integrated into the defensive responses of the groups of cells and ultimately of the organ systems.

As the cell becomes the object of microscopic scrutiny, we get into the new world of neurotransmitters, electrical impulses going back and forth on cell membranes, enzyme systems, the emerging role of a variety of amines, the effects of imbalances, and so forth. As this information on how cells function becomes available, it is important for the mental health professionals to share with these investigators who will revolutionize our concepts of normality and abnormality the questions we want answered. Currently, with the emphasis on educational problems, the neuroscientists are heavily invested in learning how the cell learns. Eventually we also want to know about imprinting, or why and how first experiences often become the most lasting, especially in the developing organism. We want to know how the repetition compulsion works. Among many other mental and physical phenomena, we want to know about the nature and roots of the will, of rhythmic patterns, and above all, the synthetic functions of the ego. (At the same time, we should respond to the claims of some of our most respected investigators that mental phenomena such as schizophrenia are entirely biological in origin.)

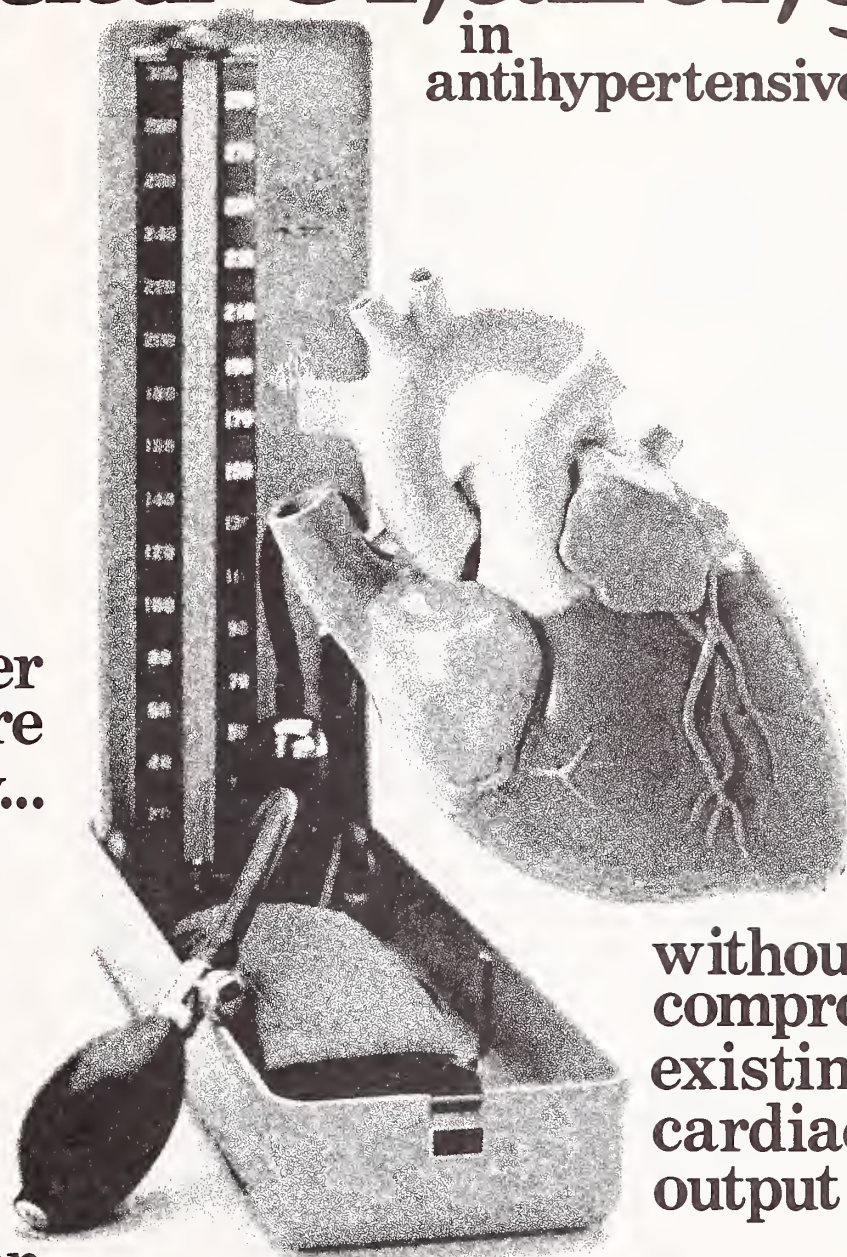
My own interest in the synthetic functions was stimulated by a little-known Navy pilot-selection project conducted at the New York State Psychiatric Institute when I was a young research associate in the early days of World War II. An ophthalmograph was used to take movies of the eye movements of normal subjects while reading, at the same time that a stress situation was developing. The stress situation consisted of a foot bellows connected to a pipe on which was placed an empty balloon next to the subjects head. As they read, they would be pumping the foot bellows. They knew that when the balloon would burst, it would be harmless; nevertheless, tension built up. In about 25 percent of these "normal" subjects, their eye movements became disorganized. At the opposite pole, close to 25 percent actually improved under stress, like the clutch hitters in baseball or the quarterbacks who do best in the last two minutes of a close football game. About 50 percent showed no change.

I was sufficiently impressed with this finding that I began to look for it in clinical problems. The tendency for thinking and performance to disorganize under stress is a significant factor as the basis for psychopathology. It can become a prime basis for the poor tolerance for anxiety. It results in one of the most anxiety-producing feelings that the human experiences—the feeling of helplessness. Clinically, one encounters all degrees of disorganization as well as all degrees of stress which produces it in given individuals. In its most extreme form, it is found in

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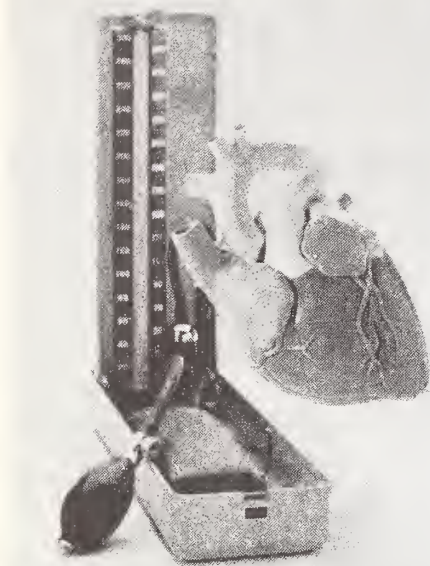
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Contraindications: Active hepatic disease, such as acute hepatitis and active cirrhosis; if previous methyldopa therapy has been associated with liver disorders (see Warnings); hypersensitivity.

Warnings: It is important to recognize that a positive Coombs test, hemolytic anemia, and liver disorders may occur with methyldopa therapy. The rare occurrences of hemolytic anemia or liver disorders could lead to potentially fatal complications unless properly recognized and managed. Read this section carefully to understand these reactions.

With prolonged methyldopa therapy, 10% to 20% of patients develop a positive direct Coombs test, usually between 6 and 12 months of therapy. Lowest incidence is at daily dosage of 1 g or less. This on rare occasions may be associated with hemolytic anemia, which could lead to potentially fatal complications. One cannot predict which patients with a positive direct Coombs test may develop hemolytic anemia. Prior existence or development of a positive direct Coombs test is not in itself a contraindication to use of methyldopa. If a positive Coombs test develops during methyldopa therapy, determine whether hemolytic anemia exists and whether the positive Coombs test may be a problem. For example, in addition to a positive direct Coombs test there is less often a positive indirect Coombs test which may interfere with cross matching of blood.

At the start of methyldopa therapy, it is desirable to do a blood count (hematocrit, hemoglobin, or red cell count) for a baseline or to establish whether there is anemia. Periodic blood counts should be done during therapy to detect hemolytic anemia. It may be useful to do a direct Coombs test before therapy and at 6 and 12 months after the start of therapy. If Coombs-positive hemolytic anemia occurs, the cause may be methyldopa and the drug should be discontinued. Usually the anemia remits promptly. If not, corticosteroids may be given and other causes of anemia should be considered. If the hemolytic anemia is related to methyldopa, the drug should not be reinstituted. When methyldopa causes Coombs positivity alone or with hemolytic anemia, the red cell is usually coated with gamma globulin of the IgG (gamma G) class only. The positive Coombs test may not revert to normal until weeks to months after methyldopa is stopped.

Should the need for transfusion arise in a patient receiving methyldopa, both a direct and an indirect Coombs test should be performed on his blood. In the absence of hemolytic anemia, usually only the direct Coombs test will be positive. A positive direct Coombs test alone will not interfere with typing or

cross matching. If the indirect Coombs test is also positive, problems may arise in the major cross match and the assistance of a hematologist or transfusion expert will be needed.

Fever has occurred within first 3 weeks of therapy, sometimes with eosinophilia or abnormalities in liver function tests, such as serum alkaline phosphatase, serum transaminases (SGOT, SGPT), bilirubin, cephalin cholesterol flocculation, prothrombin time, and bromsulphalein retention. Jaundice, with or without fever, may occur, with onset usually in the first 2 to 3 months of therapy. In some patients the findings are consistent with those of cholestasis. Rarely fatal hepatic necrosis has been reported. These hepatic changes may represent hypersensitivity reactions; periodic determination of hepatic function should be done particularly during the first 6 to 12 weeks of therapy or whenever an unexplained fever occurs. If fever and abnormalities in liver function tests or jaundice appear, stop therapy with methyldopa. If caused by methyldopa, the temperature and abnormalities in liver function characteristically have reverted to normal when the drug was discontinued. Methyldopa should not be reinstituted in such patients.

Rarely, a reversible reduction of the white blood cell count with primary effect on granulocytes has been seen. Reversible thrombocytopenia has occurred rarely. When used with other antihypertensive drugs, potentiation of antihypertensive effect may occur. Patients should be followed carefully to detect side reactions or unusual manifestations of drug idiosyncrasy.

Use in Pregnancy: Use of any drug in women who are or may become pregnant requires that anticipated benefits be weighed against possible risks; possibility of fetal injury can not be excluded.

Precautions: Should be used with caution in patients with history of previous liver disease or dysfunction (see Warnings). May interfere with measurement of: uric acid by the phosphotungstate method, creatinine by the alkaline picrate method, and SGOT by colorimetric methods. Since methyldopa causes fluorescence in urine samples at the same wavelengths as catecholamines, falsely high levels of urinary catecholamines may be reported. This will interfere with the diagnosis of pheochromocytoma. It is important to recognize this phenomenon before a patient with a possible pheochromocytoma is subjected to surgery. Methyldopa is not recommended for patients with pheochromocytoma. Urine exposed to air after voiding may darken because of breakdown of methyldopa or its metabolites.

Stop drug if involuntary choreoathetotic movements occur in patients with severe bilateral cerebrovascular disease. Patients may require reduced doses of anesthetics; hypotension occurring during anesthesia usually can be controlled with vasopressors. Hypertension has recurred after dialysis in patients on methyldopa because the drug is removed by this procedure.

Adverse Reactions: *Central nervous system:* Sedation, headache, asthenia or weakness, usually early and transient; dizziness, lightheadedness, symptoms of cerebrovascular insufficiency, paresthesias, parkinsonism, Bell's palsy, decreased mental acuity, involuntary choreoathetotic movements; psychic disturbances, including nightmares and reversible mild psychoses or depression.

Cardiovascular: Bradycardia, aggravation of angina pectoris. Orthostatic hypotension (decrease daily dosage). Edema (and weight gain) usually relieved by use of a diuretic. (Discontinue methyldopa if edema progresses or signs of heart failure appear.)

Gastrointestinal: Nausea, vomiting, distention, constipation, flatus, diarrhea, mild dryness of mouth, sore or "black" tongue, pancreatitis, sialadenitis.

Hepatic: Abnormal liver function tests, jaundice, liver disorders.

Hematologic: Positive Coombs test, hemolytic anemia. Leukopenia, granulocytopenia, thrombocytopenia.

Allergic: Drug-related fever, myocarditis.

Other: Nasal stuffiness, rise in BUN, breast enlargement, gynecomastia, lactation, impotence, decreased libido, dermatologic reactions including eczema and lichenoid eruptions, mild arthralgia, myalgia.

Note: Initial adult dosage should be limited to 500 mg daily when given with antihypertensives other than thiazides. Tolerance may occur, usually between second and third month of therapy; increased dosage or adding a thiazide frequently restores effective control. Patients with impaired renal function may respond to smaller doses. Syncope in older patients may be related to increased sensitivity and advanced arteriosclerotic vascular disease; this may be avoided by lower doses.

How Supplied: Tablets, containing 125 mg methyldopa each, in bottles of 100; Tablets, containing 250 mg methyldopa each, in single-unit packages of 100 and bottles of 100 and 1000; Tablets, containing 500 mg methyldopa each, in single-unit packages of 100 and bottles of 100.

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many autistic and psychotic children and adults. In other words, the resulting helplessness under inner or outer stress must be defended against even if it means regression to or arrest at a more primitive level to achieve homeostasis. The youngsters with the mild to severe handicapping conditions who become disorganized under the stress—such as unmet dependency needs or lack of trust in themselves and others—are not readily accessible to remedial programs. This group includes those with the much abused syndrome of minimal brain damage and those with learning disabilities. They are in sharp contrast to those who organize better under stress and who overcome their handicaps much easier and earlier. It is interesting that there are three recent reports of a variety of disorganized patterns in eye function in adult schizophrenics.¹³

Several pioneers in psychoanalysis were concerned with the synthetic functions and the integrative capacities of the developing mind. Hartmann's attention to the process of deneutralization and to adaptation as related to integration is an illustration.¹⁴ Nunberg correlated the synthetic function with the development of wide variety of other ego and superego functions.¹⁵ From the neurophysiological viewpoint, Jasper has brought up to date the relationship between electrical activity of the brain and mechanisms of cerebral integration.¹⁶ Since the groups that need each other have been eyeing each other for at least 40 years, a few more or less successful trial marriages are taking place. McLean has correlated the striate (reptilian) brain with emotions and integration of the signals from the internal and external environment.¹⁷ He correlates the neocortex with ideas and procreation, as related to creativity. Mental Health needs this kind of marriage. Let us do more of the courting.

In still another direction a new marriage has taken place between sociology and biology. The eminent biologist, Wilson, of Harvard has created "sociobiology," which in turn has turned to mental health for needed answers. One of sociobiology's concerns is with the "glue" that holds societies together, at all levels from the insect world to the mammals, including man. Wilson has named this "glue" altruism.¹⁸ Trivers, his associate, has annotated complex forms of altruism in the context of survival.¹⁹ For example, among the wasps there is one family which befriends and helps another, which in turn is the enemy of the predatory wasps who attack the first group. Sociobiology is looking to us to help their understanding of the nature of what we call attachment and dependency, which, once established in the human on an individual basis, become translated into group functioning. Along with this, sociology is concerned with what could be a whole

new dimension in our culture—the breakdown of the human family. Sociologists point out that the "glue" which holds families together increasingly does not hold and asks mental health why.

The field of urban planning and the science of human settlements have recently realized that cities should be structured around meeting the developmental needs of our young. This would be a simpler problem if we were not interfering with nature. In fact, as we try to mature, the creature man, as a 6-year-old, is in the process of perverting nature. We began like the other creatures of the earth with two major interests and functions—survival and preservation of the species. As, in terms of Porgy and Bess, the living became easier and easier, there was more and more opportunity for a range of other satisfactions, particularly in the more advanced countries. Preservation of the species, while still as important as before, has had to compete with more and more priorities and preoccupations of modern man. This has been reflected in the way modern man has built his cities. The city is increasingly the place in which we rear our young, and we have forgotten to build them with preservation of the species in mind.

The child's first living environment is the womb, and here, too, man has perverted nature. "The environment of the womb cannot be guaranteed to be perfect or without possible harmful, induced impairments to the possible future child . . . even if natural fertilization and the uterine environment have been selected over long evolutionary ages, still there are 'mistakes' in nature and the uterine environment turns out to be harsh to many. The incidence of these 'natural' damages is not negligible . . . Genetic mutations are constantly taking place, producing by chance changes in individual babies," as Monod dramatically points out,²⁰ even though Einstein refused to believe that "God plays dice."

We are only beginning to be aware of the magnitude of disease produced by genetic or congenital abnormalities: approximately 5/1000 newborns in the U.S. have major chromosomal abnormalities and 10/1000 have inherited metabolic disease. Thus, in the U.S. alone, every year 20,000 children are born with chromosomal or metabolic disorders. These are responsible for 25 percent of all hospital bed occupancy in the U.S. Science has made it possible for these children to live when in the past they died. Tagani Al Mahi, the distinguished psychiatrist in the Sudan, points out that the deaf cannot survive in the African bush, and that there are no stutterers there.²¹

All this tells us how man has perverted nature in the earliest development of our young. The process of natural selection has been partially reversed. We can keep more than 60-70 percent of our handicapped

children alive and functioning who earlier would have died or been born dead. Recent experiments demonstrate the possibility of taking a gene for a specific metabolic function from the bacterium and place it effectively in the cell of an organism with a missing gene for that function. Therefore, if we are to be true to our too often violated ethics and value systems as they relate to the sacredness of human life, we have a dual responsibility as we plan the city for human development. On the one hand, we have the mission to enhance the potentials of the normal "average" child, as the founder of humanistic psychology, Abraham Maslow, pressed us. On the other hand, the humanistic city must take into account those who start life with defects in their basic equipment.

Yet, the reverse is beginning to happen. From the viewpoint of the developmentalist, cities too have developmental stages. It used to be that the end result of this developmental process was that nature killed the cities. However, now we can keep the cities alive. We even venerate the aged parts of them, sometimes when the only thing to venerate in these old components is their age, since they were quite uncomfortable to live in by modern standards. Should we look at the components of our cities as experiments of man and then think in terms of survival of the fittest? What is fittest should be measured in terms of its usefulness in enhancing, certainly not retarding, human development. We are on the leading edge here of an exciting and meaningful dimension and mission for our cities which involves the working and living together of mental health with urban planning. Let us widen that edge so that it dominates the future.

Some wise and/or wily politicians have called on the techniques of mental health professionals for case histories of their colleagues to learn what motivates them and where they are vulnerable and movable. But at the same time that we extend ourselves to meet all these needs, we should look at ourselves. It is no secret that mental health workers are in a high-risk occupation. The suicide rate for psychiatrists is higher than the high rates for other medical disciplines. No one is looking at the social workers and psychologists' mental health. As one social worker describes her work for one day, "I've dealt with a bomb a minute or been through a decompression chamber." There should be support for the emotional endurance of the mental health worker.

The concept of applied mental health is spreading in ever increasing directions. It has been invited not only into politics, but also into the orbits of the fields of economics, the secret services, defense, labor, consumer affairs, the media, as some examples. We need a large army to meet all the domestic and cross-

national calls for the services and concepts which Clifford Beers launched. Freud once called for a new form of a Salvation Army. Maybe we also need a new concept of a Department of Defense. Like what was wished for Abou Ben Adam, "Clifford Beers, may your tribe increase." Then we can truly say that the title of Nora Sterling and Nina Ridenour's dramatization based on Clifford Beers' autobiography becomes, as it should be, "My name is Legion," no longer only in terms of how many mentally ill we have in America, but how many fighters and helpers we have in this tradition he began here!

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Month in Washington

The American Medical Association has assailed the government's release of the names of 995 physicians who last year received \$100,000 or more from the Medicaid program, terming the action "nothing less than an attempt at guilt by innuendo".

"It simply makes a tough practice tougher for the thousands of dedicated, honest ghetto physicians," declared James Sammons, M.D., Executive Vice President of the AMA.

A total of 2,533 Medicaid providers, including dentists, pharmacies and laboratories as well as physicians, was released by the Social and Rehabilitation Service (SRS) of the Health, Education and Welfare Department. The Agency said the list was requested under the Freedom of Information Act by news media and others. Under the Act, according to the Agency, the information must be provided.

"The fact that these medical providers received the stated amounts from the Medicaid program should not be construed as any evidence of wrongdoing, nor do amounts listed necessarily represent 'earnings' or 'profits'," SRS spokesman said, adding that it had no information as to the size of staffs employed by the individual doctors, or the number of separate offices they may maintain.

In addition to the 995 physicians, there were 312 dentists, 127 labs, and 1,099 pharmacies on the list released by HEW. The physicians included 542 individual practices and 453 group practices.

States with the largest numbers of physicians on the list were California, 300; Illinois, 144; New York, 113; Michigan, 83; Texas, 62; Ohio, 41; and New Jersey, 28. The names and addresses of all physicians, including those in the group practices, were contained in the massive, inch-thick document.

AMA's Dr. Sammons asked, "Does HEW think these doctors are guilty of fraud? Then let HEW say so. Does HEW think they are guilty of violation of ethics? Then let them give us the names and we will investigate."

"The AMA favors prosecution to the fullest extent of the law of any person—physician or otherwise—who defrauds patients or the government," Dr. Sammons said, "But we are tired of doctors being made the whipping boy by publicity-seeking bureaucrats and politicians. If they want to clean up Medicaid and Medicare let them go after the Medicaid Mill and nursing home operators who prosper in every major city with political protection. That's the root of the corruption and the fraud and abuse."

"This releasing of names is nothing less than an attempt at guilt by innuendo. It simply makes a tough practice tougher for the thousands of dedicated, honest ghetto physicians. If HEW wants to drive medical care out of the ghetto completely, it has certainly hit upon a highly effective method."

Patient package inserts for almost all drugs, one of the major demands of the consumer movement, with their attending problems and concerns were discussed at a two-day symposium here recently. The session was sponsored by the AMA, the Drug Information Association, the Food and Drug Administration and the Pharmaceutical Manufacturers Association.

The patient insert should not be confused with the package insert. Years ago Congress approved the requirements for the package insert for prescription drugs, apparently in the mistaken belief much of this information would get to the patient. Most of it went to pharmacists; none was required to be given to patients.

There were hearings in the last Congress on legislation introduced in House and Senate aimed at providing patients, with certain exceptions, insert information on the prescription drugs they receive.

FDA Commissioner Alexander Schmidt, M.D., told the symposium the consumer has a right to know about the medicine he is taking. "There is increasing evidence that a high proportion of Americans either do not understand the prescription instructions or do not follow them," Dr. Schmidt said. He contended there is a lack of effective communication often between physician and patient on drug information.

The information supplied patients must not be as detailed as the warnings required in advertising. This would be "an invitation to hypochondria," said Dr. Schmidt. Rather the information should be in plain English, factual, and explain why the drug is being taken, major side-effects to watch out for, and when to report reactions to the physician, according to the FDA Chief.

William Barclay, M.D., AMA Group Vice President for Scientific Publications, said carefully prepared information about selected drugs is desirable and could be of service to patients, physicians and pharmacists. However, Dr. Barclay cautioned that there is a clear danger that the disclosure could be so alarming as to discourage use of drugs that are vitally needed.

One of the major questions to be answered is how the insert would be distributed. "Obviously, the physician would rather not have the responsibility of stocking in his office perhaps thousands of brochures," he said.

*Prepared by the Washington, D.C.,
Office of the American Medical Association*

Of even greater importance, is the liability and other factors involved when physicians in certain cases for the sake of their patients either want no insert provided or want to suggest doses or other information that might run counter to the insert's material.

John Adams, PhD, Vice President of the PMA, said non-prescription drugs contain far more patient informational material than the stronger prescription drugs. However, the patient package insert could cause severe strain on the physician-patient relationship, he said. "An adequate explanation of the risks and benefits might be impossible in a brief description."

Joseph Onek, Counsel for the Center for Law and Social Policy, said physicians don't have the time to tell their patients all they need to know about drugs. Patients forget anyway. He suggested that a priority list be made up for the inserts, starting with all drugs used in pregnancy, then tranquilizers and barbiturates.

The Social Security Administration is asking the public for help on how much information, including medical data, should be disclosed from Social Security records.

"Social Security needs to change its regulation to make it conform with the Privacy Act, the Freedom of Information Act, and the new government in the Sunshine Act," a spokesman said.

"An important issue underlying these laws is the basic conflict between the public's right to know and the right of privacy of the people whose records are kept by Social Security," SSA Chief James Cardwell said. "We will need to resolve that conflict in our regulation, and we want the public's help."

Social Security said the revised regulation must address the basic information about an individual collected for purposes of administering the Social Security Act vs. interchange of such information with state or federal agencies to further efficient administration of other benefit programs, or to meet other governmental needs—a further concern is the public's right to know.

What personal information (including the Social Security Number) should be disclosed by SSA without the consent of the individual in the following situations:

- (a) for entitlement or potential entitlement to other local/state/federal benefits or service;
- (b) for investigative or prosecution purposes.

Among other questions posed were whether there should be limitations on disclosure of medical information to third parties and special procedures for disclosing medical information to the subject individual, and to make public fees paid to individual physicians, incorporated individual physicians, and other providers of medical services.

Moving to carry out a new federal law, HEW has made appointments designed to give higher priority to health education, health promotion, and disease prevention activities.

The new law, the National Consumer Health Information and Promotion Act, was approved by the Congress last summer.

Assistant Secretary for Health, Theodore Cooper, M.D., announced that Roger O. Egeberg, M.D., Special Assistant to the Secretary for Health Policy, will serve as his special assistant for health education.

A staff office—the Office of Health Information and Health Promotion—will be set up in the office of the Assistant Secretary for Health. Named as interim director of that office was Ms. Jane Fullarton.

Dr. Egeberg will have overall responsibility for health education policy and for developing better working relationships with outside organizations engaged in health education activities.

The new law directs the office of health information and health promotion to:

- **coordinate health information;
- **coordinate such activities with the private sector;
- **facilitate coordination with other federal agencies, and professional organizations, citizens organizations, and public interest groups;
- **and, coordinate the operation of a national clearinghouse on health information, promotion, and prevention activities.

Ms. Fullarton is currently the director of the Division of Health Research, Office of Policy Development and Planning, Office of the Assistant Secretary for Health.

A National Academy of Sciences panel has called for a 10 percent decrease in the ratio of hospital beds to population. Claiming that a surplus of short term general care beds is contributing to higher medical costs. The panel said a national health planning goal should be to reduce the present ratio of 4.4 beds per 1,000 persons to 4.0 by 1981.

This would be accomplished by curtailing hospital construction and closing down some existing hospital facilities.

The report sponsored by the Academy's Institute of Medicine also recommends shifting from the present system of retrospective cost reimbursement to a prospective rate-setting system. The report states the present third-party system "virtually guarantees the widespread development of excess bed capacity and encourages unnecessary and inappropriate treatment."

CONNECTICUT MEDICINE, JANUARY, 1977

Reflections from the Dean's Office

Robert U. Massey, M.D.

Medicine and medical education in North America will be forever in debt to The Carnegie Foundation for the Advancement of Teaching. It is impossible to say with certainty of any event in history that it was responsible for this or that effect, but during the past 66 years the course of medical education and research, and also of practice, has been in large part set by Abraham Flexner's Bulletin Number Four, *Medical Education in the United States and Canada*.

The most recent Carnegie report, *Progress and Problems in Medical and Dental Education*,¹ gives temperate consideration to the implications of increasing Federal financial support of health professional education, especially since 1971, and of the Federal control inherent in that support. The report issues three warnings which ought to be stated in full so as to avoid misunderstandings:

FIRST WARNING: *We are in serious danger of developing too many new medical schools, and decisive steps need to be taken by both federal and state governments to stop this trend.*

We recommend only one new medical school in a community that now has no existing or developing school—Wilmington, Delaware. We also see a need for one new dental school in Arizona.

SECOND WARNING: *There is a critical danger that concern over geographic maldistribution of health manpower and overspecialization in medicine will lead to excessive and unwieldy federal controls rather than to policies emphasizing incentives to effect the required changes.*

THIRD WARNING: *The time has come to cease relying on foreign medical graduates to meet the need for physicians in the United States. The number of U.S. medical graduates is now increasing so rapidly that we can expect ample future increases in supply from existing medical schools.*

The tide of scientific and technologic advance which has been rising in Western culture for three centuries now floods over the entire world. The West must discover ways to be responsible in this world change which it has wrought without returning to the imperialistic devices of the past. Sakharov² suggested that one way or another the developed nations may need to double-tithe their treasures of knowledge and capital.

By 1985, according to projections of the Bureau of Health Resources Development, there will be between

207 and 217 physicians per 100,000 population in the United States. Only in Israel and in the Soviet Union are ratios higher; in Israel there has been a large immigration of professionals, and in Russia physicians perform many roles assigned to paraprofessionals here.

In 1910, when Flexner wrote his report, the ratio in this country was about 176 physicians per 100,000 population. This was too many, in his view, and he made the shrewd observation, anticipating today's concern, that "even long continued over production of cheaply made doctors cannot force distribution beyond a well marked point."³ A look abroad might suggest a further observation: government regulations cannot do it either.

For too long we have imported physicians from underdeveloped and developing nations until now these foreign medical graduates represent about 40 percent of all new physicians licensed in the United States. The director of a medical school in Delhi suggested to me that we could help India by not enticing away more Indian doctors, and by urging many to return home where the need is great.

From its abundance America should now begin to export or to lend our physicians, scientists, and educators. We have always done this, but with the decline in missionary zeal, our exports have been sharply reduced in number and too often associated with commercial or military interests. Ways could be found to make voluntary programs attractive. Project HOPE is an example.

As a people we are recapturing our sense of national moral purpose. We shall not repeat the missionary efforts of the nineteenth century, but perhaps we shall learn to share our blessings without disrupting alien cultures. The Carnegie Council suggests that we might "look forward to the time when the United States will contribute to raising the quality of health care in underdeveloped countries by exporting U.S.-trained physicians rather than depending on foreign countries for its supply."

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ROBERT U. MASSEY, M.D., Dean and Professor of Medicine, University of Connecticut School of Medicine, Farmington.

Report of the President to the House of Delegates at its Semi-Annual Meeting, November 17, 1976

Hilliard Spitz, M.D., New London

I would like to discuss with you at this time some of the events which have transpired in the seven months since we last met and to make comments regarding several of them. (1)—*Professional Liability* has been one of our chief concerns. I will discuss this in two separate areas. First, I will comment on our relations with Aetna. I believe there is a good deal of misunderstanding as to just what this relationship is. There is no formal contract between Aetna and CSMS. The only actual contract that does exist is between each physician, individually, and the insurer, Aetna. Several years ago, before professional liability reached its present crisis stage, Aetna proposed to make available insurance policies to the doctors of Connecticut only through a program which required membership in the Society. It was Aetna's belief that, in this manner, utilizing the endorsement of membership in the state society and working with the review panels set up by the Society and with the opportunity to educate the doctors regarding professional liability that this could offer us better premium values. CSMS agreed to sponsor the program and serve in an advisory capacity but the final direction of the program rested with Aetna. Despite the considerable increases in premiums which we have had, the program does seem to have been a good one for us. We have been assured that the program will continue for at least another 4 years and, in general, our premiums have compared favorably with those in other states—in fact, considerably better than most. This year our over-all increase in premiums was satisfactory. However, there was a reclassification, the principle of which I must say, in all fairness, was concurred in by most physicians of the state. There was a good deal of complaint that doctors doing similar work were paying vastly different premiums. Reclassification was an attempt to end this inequity by having the doctors themselves indicate what the nature of their work was. I must emphasize that no one in CSMS had anything at all to do with the assignments of classifications and that committee members had no prior knowledge of their own class. The reclassification was made on the basis of information supplied by the individual doctors and using standard Insurance Services Office (ISO) tables of classification. There is no question that certain inequities still prevail. I believe Aetna realizes that this is the situation, and a subcommittee of our Professional Liability Committee is working with them to try to correct these inequities. I would point out to you that it is of no concern of Aetna's how we are classified. A certain total amount

of premium dollars must be realized and the individual premiums will depend somewhat upon the numbers of physicians in each class. I think it is fair to say that some few are paying more than their share. An effort will be made with Aetna to correct this also but I am afraid that the correction will be for next year and not for this.

The other development for this year is the removal of the need for our consent to settle a case. The Professional Liability Committee has argued against this from the moment we first heard of it. We are still in discussion with Aetna trying to work out a procedure that can be undertaken when a disagreement about settling does result. I can advise you that Aetna's chief claim in this respect is that the doctor is often dead set against settling a claim at its onset, when the settlement could be quite reasonable, but then at a later date, when the case is coming to trial, he reverses himself, does not want to go to court and the settlement at that time is appreciably more.

The other aspect of professional liability is: What can we do to lower the awards? No one believes that any major progress can be made through legislation. The main answer still has to do with our professional activity and patient relationship. However, we do believe some modification of the tort system can work to our advantage. We are therefore considering legislation to be submitted to the 1977 General Assembly. Our plans are not finalized but at this time the following are being considered:

- 1) An Act concerning peer review immunity.
- 2) An Act concerning collateral source payments.
- 3) An Act concerning voluntary and non-binding pre-trial screening panel for medical malpractice cases.
- 4) An Act concerning elimination of ad damnum clause in malpractice suits.
- 5) An Act concerning installment payments of malpractice awards.

(2)—*HSA's*. I must mention briefly P.L. 93-461, not because there have been any really new developments but because it carries such potential for planning and regulation of medical affairs with such little participation of the medical profession. I would refer you to the August 1976 issue of "Connecticut Medicine" for the report of the AMA Board of Trustees to the House of Delegates for a fuller discussion of this matter. The AMA testified against the bill before both the Senate and the House of Representatives and urged its veto by the President on the basis of its imminent danger to the provision of quality medical care. However, at present

it is the law of the land and we must try to live with it. The HSA's in Connecticut have been established already. However, there are many committees of the local agencies which are still to be formed. I would urge that doctors seek as much representation on these committees as possible to insure maximum medical input. Meanwhile, the state of North Carolina is questioning the constitutionality of the law in that it abridged the rights of the state and the AMA has entered the case as a "friend of the Court".

(3)—*Federal Trade Commission Action*. In December 1975, AMA, CSMS and New Haven County Medical Association were served papers by the Federal Trade Commission complaining that they have violated Section 5 of the Federal Trade Commission Act. It is stated that there exists an agreement "to prevent or hinder members from A) soliciting business by advertising or otherwise; B) engaging in price competition; and C) otherwise engaging in competitive practices." The claim states further that these are embodied in the "Principles of Medical Ethics" and that in enforcing the "Principles of Medical Ethics" A) "prices of physician services have been stabilized, fixed or otherwise interfered with; B) competition between medical doctors in the provision of such services has been hindered, restrained, foreclosed and frustrated; and C) consumers have been deprived of information pertinent to the selection of a physician and of the benefits of competition."

The Council of CSMS, feeling that this claim presented a dangerous threat to the professional status of the doctor, voted to defend this action in court and joined forces with the AMA, securing our own legal counsel to work with that of the AMA. The first effort was to claim that we were not engaged in interstate activity and therefore did not fall under the aegis of the Federal Trade Commission. This claim, however, was denied and the case is now set to be heard on June 6, 1977. In the meanwhile agents of the FTC have appeared at the offices of NHCMA and CSMS, going through our files and photostating a tremendous number of documents of all sorts to take back to Washington with them. The varied nature of the documents they have shown an interest in would suggest that the ultimate law suit will involve much more than the original interest in advertising. Also our inability to obtain a specific complaint against us leads us to fear that much more in the way of regulation of medicine is intended.

(4)—*Nurses Strike at Windham Hospital*. CSMS took no active part in this matter. At no time did we issue any statement nor participate in any discourse regarding this strike. However, we were keenly interested in some of the issues and sought to be informed of its programs by members of our Council from

Windham County. The legal time allowed for settling such a strike has passed and the matter is not a viable issue at present. However, one issue of major importance in the Windham strike, namely the "Role of the Nurse" is one that many of us may have to meet in our own hospitals. CSMS opposed the 1975 revision of the Nurse Practice Act which gave the nurse the right to *diagnose* response to illness. However, as you know, the act was revised.

The "Role of the Nurse" became one of the major issues of the strike. The hospital Board felt that in seeking autonomy for the nurse in nursing affairs, the proposed role of the nurse went beyond bounds that they could accept. There was some feeling that nursing was unwilling to accept limitations necessary for the proper interaction of all concerned in the care of the patient; that nursing autonomy as the nurse interpreted the provisions of the Nurse Practice Act was placed above all other considerations. We do have in Connecticut a State Joint Practice Committee (a committee of equal number of doctors and nurses). It is the goal of this committee to establish joint practice groups in all the hospitals of the state. I would hope that in the future, if such issues arise, they could be referred to such a committee and that doctors and nurses working together could find a solution to these problems.

(5)—*Hospital Cost Commission*. Finally, I wish to spend a few moments on a matter about which, as President of the Society, I have received many letters from doctors throughout the state deploring the action of the Commission and requesting action by our Society. I am not here to defend the Commission. I have heard complaints about their complete disregard for the individual hospital situation and I have heard counter-claims of their line-by-line evaluation of each budget. I do not feel that I have enough reliable pertinent information to either condemn or condone the Commission's present actions. However, I would like to assume the role of the devil's advocate for a moment and ask that you consider some of the more far-reaching implications of those actions.

Medical costs are rising and, as we are usually given to point out, the marked rise is not in doctors' fees but in other areas and particularly in hospital costs. The increasing cost of medical care outstrips the general cost of living index by a considerable amount. The population at large is aware of this fact. They are seeking moderation of medical costs. It is because of this fact that we face so much of the government involvement in medical affairs in recent years. Government must be responsible to its constituents and one message that comes across loud and clear is dissatisfaction with the rapidly escalating cost of total medical care. We say that when the government takes

over the management of any enterprise, waste and inefficiency prevail. I don't think there is any question about this but if costs are to be contained, and if the government is not to do it, who is? We must assume the leadership in this endeavor and we must do it now. Cost containment does not mean sacrificing quality care. However, it does mean re-examination of some of our procedures and institutions in an effort to reduce costs. Let me raise just a few questions. How much money is spent in hospital emergency rooms and clinics in providing primary health care which could be handled just as well in private offices? It might be less convenient for us, and it might involve some changes in insurance coverage, but it would certainly reduce the over-all cost of health care and it most certainly would not affect the quality of care. Along similar lines, how often do we see a patient well known to one of us who gets to an emergency room with a complaint and is not known to the person who sees him there? The result is a multiplicity of tests,

often duplicating information we have already. This provides neither quality care nor cost containment. Sub-specialists have provided a great boon to our ability to care for patients. They have improved the quality of medical care to a great extent. Still, I think we can ask the question: With so many of them being full-time at the hospital, do they provide better service when hospital-based? If not, the question rises again as to the cost of their services when it has to be absorbed into the built-in overhead of a hospital budget. The questions of regionalization and duplication of services raise further questions. Again I am not saying that reduction of hospital budgets need be the answer. I am saying, however, that an answer is needed and if we don't like somebody else's plan we should be prepared to offer one of our own.

There are other pertinent matters, but I believe that the ones I have discussed are probably of prime importance at this time.

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EDITORIALS

Commentary

The mental hygiene movement in the United States was formally established in Connecticut on May 6, 1908 when the first meeting of the Connecticut Society for Mental Hygiene was called by Clifford Beers in what is now the Faculty Club of Yale University.¹ Beers had personal knowledge of mental illness. His experience convinced him that the recognition, prevention and treatment of mental illness were too important to be left in the hands of professionals alone. In his classic account, *A Mind That Found Itself*,² Beers did what others feared and avoided; he treated illness of the mind with the same open-mindedness and acceptance that are traditional for injury or illness of the body.

In the second Clifford Beers Memorial Lecture³ Reginald S. Lourie has made it abundantly clear that because of the nature of mental illness it will be necessary to maintain unending efforts to maintain a rational dialogue about these human ailments. Only through a rational approach can we correct the ubiquitous, fearful, superstitious attitudes that exist toward psychiatric conditions and mental deviations, both inside and outside the health professions.

Because of our highly charged and conflicted attitudes about that part of the brain's functions termed the mind, we are inconsistent about the criteria we use to designate psychological and emotional difficulties. Much of this is due to our lack of precise knowledge about human development and personality; but much of it is also due to the question of personal responsibility for individual behavior. Philosophically, we wonder, couldn't the individual will himself to be or do differently, to shape up, to function well and to help others?

In the case of children, especially in regard to rebellious, delinquent or criminal behavior, there is a vocal group who find comfort in the conviction that if children are in trouble, the responsibility for their difficulties can and should be laid squarely, oftentimes punitively, on the shoulders of the parents. This narrow, at times bigoted, point of view obscures our understanding and our efforts to be helpful within the limits of our capabilities. Even the definitions of child and adult are complex and changing, depending on the functions, behavior and services that are implied when we speak of the needs and rights of children and of adults.⁴ Thus, the issue of what causes mental illness and who is responsible for the behavior that is presumed to be an expression of mental illness should always be approached with an awareness of our strong tendency toward irrationality. Often we give in to our tendency to substitute a social prejudice for objective knowledge. For example, until the autistic psychoses of early childhood were better understood, there was a strong tendency to assume that this condition was caused by the aloof, detached behavior of parents; rather than to assume that these children were different from birth and that they made parenting most difficult. Other examples can be found in defining the individual's right to make a decision about aborting an unwanted child or the rights of the patient who is hospitalized for a psychiatric condition.⁵ At what age is the individual a child whose decision should be made by the adult responsible for his care; and at what age is the individual an adult in law authorized to make his own decisions? The criteria for emancipation are not nearly so conflicted in regard to the decision to arrange for medical diagnosis and treatment when the individual has a suspected appendicitis or physical injury, as when the individual has a condition that carries highly-charged social freight, such as an unwanted pregnancy or

behavior implying a psychiatric condition. Does biological competence confer psychological and legal competence?

Defining the limits of and refining our knowledge about human development and behavior is an urgent task if we are to avoid the overselling, under support, and irrational attitudes associated with our concerns for mental illness and mental health. In his Clifford Beers Memorial Lecture, Reginald S. Lourie has provided us with a rich perspective to facilitate the defining and clarifying process in order to establish and maintain a rational approach to mental illness and mental health. This process, having medical, ethical and value preference implications, is a widening one in our society at this point in historical time. By being increasingly aware of the complexity of the social, psychological and biological interactions that are involved not only in mental illness and psychosomatic disorders but also in primarily physical disorders (e.g., diabetes mellitus, mental retardation and spina bifida with meningomyelocele), we should be able to be more humane. We also can expect, in this way, to be more effective in providing care, preventive and curative, for those who are well and for those who are ill, physically and psychologically.

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*Sterling Professor of Pediatrics and Psychiatry;
Director, Yale University Child Study Center.*

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The Adversary System and Drug Regulation

The American legal system is, unlike the European, based on the notion that partisan ("adversary") presentations by opposing sides will somehow arrive at the truth and that justice will generally prevail. Nevertheless, most of us believe that the system fails at least occasionally although there is no way of knowing how often, or how badly, it fails.

We are now seeing a tendency for medical and scientific matters to be settled in the same fashion. A brief television appearance by a government scientist can result in a ban on cyclamates, which then proves difficult or impossible to reverse, even when new data are presented. If politicians can be convinced that a

swine flu epidemic is imminent, national resources can be mobilized, despite serious technical, scientific and legal issues, to produce, distribute and administer the vaccine to millions of people. If a Naderist group decides that HEW cannot be trusted to investigate malfunctioning of one of its branches, the job can be taken out of the hands of HEW executives.

This is not to say that public concern and dramatic confrontation need result in unwise decisions. Many badly needed reforms have been accomplished in moments of crisis as the result of mobilization of public concern. Nonetheless, it seems likely that a failure to appreciate the complexity of many biomedical issues, and to consider the implications of decisions in this area, *can* result in harm. A reasonable postulate would be, I submit, that the more complicated the cost-benefit situation for a particular problem, the less likely are wise decisions to be made on the basis of partisan confrontation and political pressures.

The adversary approach depends theoretically on an all-out, no-holds-barred black-and-white presentation by each side. A successful trial lawyer never qualifies his remarks with "on-the-one-hand but on-the-other-hand" ambivalences. His side is 100% right, the opposition 100% wrong. There is no admitting to the existence of gray areas. At the end of the process, the verdict produces a winner and a loser.

But medicine is not a cops-and-robbers game. Medical practice and scientific research are not like the Miss America Pageant or a presidential election.¹ The scientist and (even more) the practitioner deal constantly with uncertainty. They are accustomed to ambiguity, and quite properly suspicious of simplicity.

The areas of drug development, regulation and use suffer from a variety of problems that can be traced to attempts to solve biomedical problems by confrontation, publicity and politics. Regulatory philosophy is dominated by the notion that drug toxicity is the dragon to be slain, and that postponing the approval of new drugs will protect the public from untold hazards. Few have warned the public or the politicians of the harm that comes from *not* having better new drugs, or the economic costs of this philosophy. (If you haven't seen the revolutionary effects that beclomethasone can have on refractory asthmatics, you've got a satisfying surprise in store for you and your delighted patients.)

Roll, in this issue, illustrates some of the troubles that beset us today. His points are well taken and his fears well founded. He also reminds us of the mischief that can be caused by human frailty and incompetence, whether they be in government bureaucrats or academic advisory committees.

What to do? How do we avoid polarization, confrontation, passionate but counterproductive side-

taking? How do we encourage thorough and thoughtful scrutiny of all sides of an issue, with a sober cost-benefit analysis and a subsequent decision based thereon?

As Peter Barton Hutt pointed out in a speech given on June 7, 1976,² the Congressional arena is not conducive to dispassionate reflection. He describes Congressional hearings as "nothing short of staged plays," and says that they are "... prosecutorial in nature and designed to embarrass, harass, and intimidate." Nor is Hutt sanguine that we can rely on the executive branch of government, or FDA leadership. He points out that "the Civil Service Commission laws and regulations also drastically limit the ability of government officials to discipline, transfer, or discharge staff employees." Hutt suggests that private action "is the only significant control ... and its promise for the future is very bright indeed." He adds that "conscientious judicial review is the keystone to any effective control over regulatory agencies." Hutt may be right, and his words deserve attention, but the approach he espouses is not one that comes naturally to most doctors or scientists, and is not one for which they have either special training or talent. This is not the case with politicians, of course. As Boulding says:³ "... the political community ... is dominated ... by lawyers who are trained to win cases rather than solve problems." Nevertheless, speeches like Hutt's and articles like Roll's are important contributions because the public must be aware of the problems in order even to *care* about solving them. The development and introduction of new drugs should be optimized—neither pointlessly delayed nor needlessly rushed through. The situation today is far from optimal, and the prime loser in the current battle of adversaries is not the medical profession or the drug industry, but the sick. They deserve a better fate.

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Radiation-Related Thyroid Cancer

Thyroid cancer is more likely to develop in individuals who have previously had therapeutic radiation to the neck or adjacent areas.

A workshop, in September 1975, was conducted in Bethesda on this topic. In October 1975 the American Medical Association and the American Hospital Association jointly appealed to their constituencies to cope with the situation. Unfortunately, records tend to be sketchy for much of the earlier radiotherapy. Some was given in doctors' offices. Hospital records—where they have not long since been destroyed—are apt to lack the radiation factors and/or size of field. The Cancer Coordinating Committee of the Connecticut State Medical Society made exploratory probes for six months and concluded that any attempt at a retrospective study of statistical value would be very difficult, very expensive and, in the end, non-productive.

What should be done about these people who admittedly are at increased risk? Two things can be done constructively. First, every patient's history should include questioning about previous irradiation. Second, individuals with a history of irradiation of the neck, head or upper thorax should be examined at regular intervals of not over two years. Most thyroid cancers tend to grow slowly and metastasize late, thus affording time for careful appraisal and appropriate treatment.

The official recommendation of our Cancer Coordinating Committee appears in this issue of *Connecticut Medicine*. Also, an excellent coverage of the subject was published in the May/June 1976 issue of CA—A Cancer Journal for Clinicians.

E. Tremain Bradley, M.D.,

Chairman, Cancer Coordinating Committee,
Connecticut State Medical Society.

Statement of Cancer Coordinating Committee
Concerning Radiation-Related Thyroid Cancer

It is well known that individuals exposed to therapeutic doses of radiation are at increased risk of developing cancer at a later date. Therefore, physicians are urged to determine from their patients whether there has been any such previous exposure. In particular, a history of radiation to the neck—and to some extent the head and upper sternal area—is indication for meticulous and faithful periodic physical examination of the thyroid—the thyroid seeming to be especially vulnerable to post-radiation cancer.

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BOOK REVIEW

Job Plodd, Pathologist; His Trials and Tribulations. by Alvan G. Foraker, Medical Economics Book Division, Oradell, New Jersey, 1975. 204 pages. \$17.50.

This satirical account of a hospital pathologist and the people in his professional life consists of 54 essays, most of which previously appeared in *Pathologist*, the monthly magazine of the College of American Pathologists. The names of the dramatis personae and the style are reminiscent of Jonathan Swift, a resemblance heightened by the charmingly "old fashioned" typography and cover designs.

In the first two-thirds of the book the essays are sharply pointed and should have a universal appeal to physicians who enjoy a sardonic view of the world as it really is. In fact these essays as they appear originally produced anguished letters to the Editor decrying the irreverent views of life in the laboratory; there were equally staunch defenders who didn't mind being the butt of the sarcasm. Dr. Plodd's encounters with Miss Suzie Exact, his chief technologist, Charles Lummsey, the autopsy diener and Ima Tufinger, accurately reflect what the staff of any laboratory can provide. The foibles of the clinical chiefs of service, particularly Dr. B. Button, chief of Omphalology are neat composites of their counterparts in every American hospital. I am sure each clinical chief will readily recognize these foibles in his associates. Mr. Thomas Munnyfurst, the tight fisted hospital administrator is certainly familiar to all of us. The wry reflections on the competition for business between the commercial laboratory and the hospital laboratory are indeed painful to many of us. The high point of the book is entitled "The University selects a department Chairman"; the parallel to occurrences in your own alma mater is exact and chilling.

The other third of the book deals with the painful problems of the power struggles in the hospital hierarchy when a new chairman is to be chosen and the old one to be retired. This is clearly autobiographical. Although the problem is common in industry most physicians who are not "hospital based" are not familiar with it; they will be indeed after reading this!

Will you enjoy the book? Certainly if you are a hospital specialist you can't help being fascinated, sometimes amused, sometimes chilled; you won't put it down easily. For other physicians it will help to understand your hospital friends, particularly pathologists, and what makes them act as they do. The writing is good, the pace fast, and the subjects relevant; I don't think you will be bored. My own complaint is the omission of the cartoons by our own Dr. John Meyer which accompanied some of the original essays.

Roy N. Barnett, M.D.

Letters To The Editor

THE PURSUIT OF LITIGATION

To the Editor: Two hundred years ago, Jefferson changed his writing of "life, liberty and property" to "life, liberty and the pursuit of happiness." The amounts of property held by different persons affected the concepts of social equality, so alluding to the vague "pursuit of happiness" seemed less jarring than "property." Himself endowed with wealth, he found it satisfying to press for equality among men. But he could not have realized where his claims for equality and the pursuit of happiness could lead.

The sex revolution has generated a hot "pursuit of happiness," and the Robin Hoods that press on the litigation epidemic provide "have-nots" with windfalls by going after what the "haves" have got. This raises expectations for fast-buck hopefuls.

Where VD was once almost eradicated, the new sex has made it as common as the cold. The drive for "social justice" propagated by the American "right to sue" has become a pattern for the new redistribution of wealth. There was a time when people worked for money, now they seem to contend for it.

Moral decay is everywhere: Shoplifting is frequent, mugging is common, rape is rampant, burglary constantly threatens and sex is free. Young people let themselves go as readily as when they wore diapers. And the not-so-young people do not let any lawsuit income opportunity go by.

Much of that problem came from America's love affair with the automobile. When big settlements after auto collision gave some people secure nest-eggs, the game was on. And when lawyers inflated this into astronomical awards and then took 1/3 off the top as a fee, it generated the litigation epidemic that prevails today.

Premiums for auto collision became high and brought on no-fault insurance, so trial lawyers moved into the fertile field of medical malpractice.

Since the truly unfortunate should get aid, the money expended should be used to aid them, and not provide profit for someone else. And if anyone must be subject to punitive process, that should be a matter for public action by a public servant and not an income opportunity for a lawyer in private practice.

Litigation is aimed at the possession of property and that puts the capitalism which makes democracy work in grave danger. It would take a doctors' strike to make the contingent fee illegal and plaintiffs' attorneys into public servants like the prosecutors to stop this threat. Legal reform is needed if Jefferson's democracy is to survive.

Sidney Vernon, M.D.

Willimantic, CT.

SPECIAL NOTICES

PSYCHOLOGICAL ISSUES: DYING, DEATH, BEREAVEMENT AND LIVING WITH ILLNESS

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Letters

Connecticut State Medical Society members are invited to write to the Editor expressing their opinions or giving information on matters of mutual interest. As with other material, all correspondence will be subject to the usual editing and possible abridgment. Letters to the Editor should be typewritten double-spaced and must not exceed 1½ pages in length.

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SUMMARY OF PROCEEDINGS HOUSE OF DELEGATES—SEMI-ANNUAL MEETING New Haven—November 17, 1976

Reports and Resolutions

The House of Delegates received reports from the President, the Council, COMPAC, the AMA Delegates; also a number of resolutions submitted by component County Medical Associations, the Connecticut AMA Delegation and individual members of the Society.

Principal Actions Taken

- (a) **Report of the President, Hilliard Spitz, New London:** The House VOTED to accept, with commendation, the report of the President which presented his overview of such areas of current interest to physicians as professional liability insurance, Health Systems Agencies, nurses' strikes, the complaint of the Federal Trade Commission re AMA-CSMS-NHCMA limitations on advertising by doctors and the rising costs of health services.
- (b) **Budget for Fiscal 1977:** The House VOTED to approve the 1977 Budget, as submitted by the Council, and to approve the recommendation of the Council that membership dues remain at \$100.
- (c) **Termination of Authorization of Section on Neurology:** Being apprised that the subject Section has been unable to comply with the provisions of the Bylaws covering sections and section meetings for four consecutive years, and would be unable to comply in the future, the House VOTED to approve the recommendation of the Council that authorization for the Section be terminated.
- (d) **Suggestions for "Unified Dues", House of Delegates, 4/28/76:** The House VOTED to approve the recommendation of the Council that none of the suggestions be implemented. These had been offered from the floor at the previous meeting as possible alternatives to "unified

membership" (disapproved on 4/28/76). The House further VOTED to approve a Council recommendation that the Society "continue to pursue and promote the concept of unified membership among the members of the Society until such time as the membership, in the majority, shall support the adoption by the House of Delegates of a direct amendment to the Bylaws such as was presented to (and rejected by) the House on 4/28/76".

- (e) **Confirmation of Appointment of AMA Alternate Delegate:** The House VOTED to confirm the Council's appointment (10/28/76) of Guy W. Van Syckle, Danbury, as AMA Alternate Delegate to replace Morris A. Granoff, New Haven, deceased. Since Dr. Granoff had already been elected to succeed himself on 1/1/77, Dr. Van Syckle's term will carry through until 12/31/78.
- (f) **Report of AMA Delegates:** The House VOTED to receive as information a subject report which outlined and explained a number of actions taken by the AMA House of Delegates at its meeting in Dallas, Texas, 6/27-7/1/76. Some of the material presented was published in the October issue of *Connecticut Medicine*.
- (g) **Council Report on County Medical Association Review Procedures:** The House VOTED to approve an amended subject report of the Council, taking into account a supplementary subject report filed directly with the House by an Ad Hoc Committee of the Council. In essence, the report provides eleven guidelines for procedure recommended for use by the component County Medical Associations to the end that the handling of inquiries/complaints concerning physician members will be uniform throughout the state. The approved "Guidelines" follow:
 - 1. When inquiries are received at either the County Association or State Society level, the receive-

- ing office will insist upon a written statement. When the written statement is received by the County Association, the State Society will be informed that an inquiry/complaint has been filed about a specific member physician and will provide the name of the physician but not the nature of the inquiry/complaint. When the written statement is received at the office of the State Society, a copy of the statement will be kept on file at the office and a copy shall be sent to the appropriate County Association for investigative processing.
2. The county association will then forward a copy of the inquirer's written statement to its appropriate committee.
 3. The county committee then must forward to the physician a verbatim copy of the written statement and request his written commentary to be returned to the county committee within 30 days of receipt of this notification.
 4. The physician's reply must be evaluated by the county committee and appropriate action taken by the county committee to secure necessary data for proper adjudication of the inquiry.
 5. If a physician does not reply to the county committee he may be summoned before it and if he remains delinquent, appropriate punitive measures may be promulgated in accordance with the county by-laws. This could lead to loss of membership in the county and state societies with attendant hazards of such an eventuality.
 6. Within 120 days after receipt of an inquiry/complaint, the County Association shall forward a status report on same to the State Society.
 7. If after 120 days following receipt of the inquiry/complaint the matter has not been settled, the County Association shall forward further status reports to the State Society at 60 day intervals until the case is completed.
 8. All files shall be confidential and properly secured at both the county and state levels although anonymous statistical data based on these files may be released to appropriate agencies.
 9. At the conclusion of the adjudication process, if in the event that one of the aggrieved parties remains dissatisfied, appeal may be made to the Judicial Committee of the Connecticut State Medical Society.
 10. Inquiries which implicate the possibility of incompetence on the part of the physician shall be subject to the same protocol as outlined above.
 11. When necessary preliminary investigations have been made to determine the validity and substance of an inquiry/complaint, and the County Association is of the opinion that such inquiry/complaint may possibly involve a felonious action, said Association shall inform the originator of the inquiry/complaint of such opinion and suggest that the originator may take the matter to the proper law enforcement agency, and shall advise the physician concerned of the nature of the inquiry/complaint and of the action taken thereon.
- (h) **Resolution re "Physician Reimbursement for Utilization Review":** The House VOTED to adopt a substitute resolution for one introduced by the Connecticut AMA Delegation as follows:
- RESOLVED: That the House of Delegates of the Connecticut State Medical Society endorse the resolution adopted by the AMA House of Delegates which counselled "physicians *not* to seek compensation for providing the responsibilities traditionally expected of them as members of review committees of institutions at which they have medical staff appointments; and be it further
- RESOLVED: That the House of Delegates support the advocacy of the AMA "that when utilization or other review committees are mandated by government or other third parties to review patient care, compensation for the physicians involved should legitimately be claimed"; and be it further
- RESOLVED: That the House of Delegates support the advocacy of the AMA "that third party payors should accept responsibility for the costs of such review" when mandated by them.
- (i) **Resolution re "Smoking in Visual Media":** The House VOTED to adopt a subject resolution as follows:
- RESOLVED: That the House of Delegates of the Connecticut State Medical Society direct that the Society use all its means and methods of persuasion and communication, in cooperation with the American Medical Association, Connecticut units of the American Cancer Society and other health agencies, to minimize the display of smoking in all visual media, such minimization to be sought for the purposes of discouraging the presentation of visual material, particularly on TV, that depict smoking as the norm in American culture and of influencing teenagers to refrain from acquiring smoking habits.
- (j) **Resolution re "Unnecessary Surgery":** On recommendation of a reference committee, the House took no action on this subject resolution,

which dealt with several aspects of mandatory consultation or "second opinion" prior to performing surgery and found that the words "necessary" and "unnecessary" have little or no value when applied to surgery. Instead, the House VOTED to instruct the Society's Delegates to AMA to report back to the Council action taken by the AMA House of Delegates in December on this subject, and to submit another subject resolution to the annual meeting of the CSMS House of Delegates in April, 1977.

- (k) **Resolution re "Professional Liability Counter-suits":** The House VOTED to adopt a substitute resolution for one introduced by the Connecticut AMA Delegates as follows:

RESOLVED: That the House of Delegates of the Connecticut State Medical Society charge the Council to study and present at the next meeting of the House of Delegates a model strategy for assisting member physicians to initiate countersuits against attorneys and plaintiffs who file malicious malpractice suits.

- (l) **Resolution re "Right of Physician to Give or Withhold Consent to Settlement of Malpractice Claim":** The House VOTED to adopt a substitute subject resolution for one introduced by the Litchfield County Medical Association as follows:

RESOLVED: That the House of Delegates of the Connecticut State Medical Society charge the standing Committee on Professional Liability to substitute for the current unilateral settlement mechanism instituted by Aetna one which requires joint CSMS-Aetna concurrence prior to settlement.

- (m) **Resolution re "Professional Liability Coverage as a Criterion for Hospital Staff Appointments":** The House VOTED to approve the recommendation of a reference committee that the subject resolution *not* be adopted. The resolution alleged that the boards of trustees of some hospitals are using a physician's malpractice insurance status as a criterion for staff appointment and "condemned" the use of such criterion. The House was informed that the Council has already initiated an inquiry into this matter.
- (n) **Complaint of the Federal Trade Commission:** Having received a comprehensive, up-to-date statement (contained in the "Report of the Council") on the subject complaint and the Council's handling of same, the House VOTED to "endorse the actions taken by the Council thus far in defending the Society and the New Haven County Medical Association and their members against the complaint of the FTC and, in

cooperation with the AMA, in a joint defense against the subject complaint on behalf of the three defendant organizations"; and to "approve continuance of Council actions in defense of the Society and NHCMA, and the funding thereof, at least until a Commission hearing on the complaint (scheduled for June, 1977) has been held and a ruling handed down".

In a related action, the House VOTED that in the event that the House of Delegates decides to expend large sums of money on defense of the FTC complaint, the Life Members of the Society should be invited to contribute voluntarily toward meeting the costs of such defense.

In another related action, the House VOTED to direct the Council to seek to discover the originator(s) of the FTC complaint against CSMS and NHCMA.

- (o) **Resolutions Introduced from the Floor:** Having voted to receive as regular business two resolutions introduced from the floor, the House acted on same as follows:

- (1) **FCMA Resolution re Commission on Hospitals and Health Care:** VOTED *not* to adopt the subject resolution, and VOTED to endorse the Council's decision to withhold judgment on the hospitals-Commission controversy re budgets and budget cuts, pending a subject report by the Committee on State-wide Medical Planning.

- (2) **Resolution re "Watchdog Committee" Against Malpractice Abuse:** VOTED to refer this resolution (introduced by Richard Munch, Winsted) to the Committee on Professional Liability, the Ad Hoc Committee on Malpractice Insurance Study and the Committee on Legislation for joint study and appropriate action. The "watchdog committee" proposed in the resolution would function to provide "a more effective and organized front by physicians in Connecticut against the malpractice threat, both in the area of collective bargaining for reasonable malpractice insurance premiums and of collectively defending physicians".

- (p) **Resolution re "Ethics in Treatment of the 'Hopeless' Case":** The House VOTED to refer this resolution, along with the anticipated December subject report of the AMA Judicial Council, to the CSMS Judicial Committee for study and report to the annual meeting of the House of Delegates in April, 1977.

- (q) **Miscellaneous:** The House VOTED to approve two motions introduced from the floor as follows:

- (1) That, in the future, copies of resolutions

submitted too late to be considered as regular business by the House of Delegates be distributed to members of the House in advance, either with the Handbook or at the registration desk.

- (2) That each of the component County Medical Associations receive a report on the percentage of its delegates that attended this meeting of the House, and that the importance of having full representation present and participating be stressed to each component Association.

Presentations and Awards

- (1) **To CSMS Officers and County Councilors for Past Service:**

James H. Root, Jr., Woodbridge—CSMS Councilor-at-Large; Merrill B. Rubinow, Manchester, and Andrew J. Canzonetti, Waterbury—Councilor and/or Associate Councilor (HCMA); Stuart Ragland, Jr., Colebrook—Councilor (LCMA); Jerome K. Freedman, New Haven—Councilor/Associate Councilor (NHCMA); Allyn B. Dambeck, Tolland—Councilor/Associate Councilor (TCMA); Rudolph E. Klare, Woodstock, and Frank L. Bird, Willimantic—Councilor and/or Associate Councilor (WCMA).

- (2) **Special Presentations:**

To Mrs. Norman H. Gardner, East Hampton—a resolution memorializing Dr. Norman H. Gardner, deceased.

“RESOLVED: That the House of Delegates of the Connecticut State Medical Society, acting for the entire membership, express a deep sense of loss on the occasion of the death of Norman H. Gardner, M.D., East Hampton, on February 9, 1976.”

To Christie E. McLeod, M.D., Middletown—a certificate “in recognition of her dedication to the betterment of the health of the people of Connecticut. In addition to a distinguished career as pathologist at the Middlesex Memorial Hospital, Middletown, over a period of many years she has given most generously of her time and energies to the work of the Society in such diverse areas of medicine as perinatal morbidity and mortality, organ and tissue transfers, cancer, public health, physician-hospital relations and professional licensure. The Society is privileged to convey thanks and commendation to Dr. McLeod for her exemplary record of performance as an actively participating member thereof and for her outstanding contributions to medicine”.

To E. Tremain Bradley, M.D., Norwalk—an Honor Citation presented by the American Cancer Society, Connecticut Division, for “his leadership in developing the brochure ‘Follow-Up

of Cancer; A Handbook for Physicians.” The presentation was made by Romeo A. Vidone, M.D., Orange, Chairman of the Professional Education Committee of the ACS, Connecticut Division.

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Please send them to:

J. Alfred Fabro, M.D., Editor

Connecticut Medicine

160 St. Ronan Street, New Haven, Connecticut 06511

OBITUARY

EDMUND BEIZER, M.D. 1903 - 1976

Dr. Edmund Beizer died October 25, 1976 at the age of 73.

He was born and brought up in Hartford, Connecticut. He received his B.A. from Harvard College in 1925 and M.D. from the Long Island College Hospital Medical School in 1930. He served a rotating internship at the St. Mary's Hospital in Waterbury, Connecticut; and surgical internship at the Kings County Hospital, Brooklyn, New York 1931 to 1933. He returned to Hartford for private practice. In July, 1944 he decided to specialize in surgery and entered the Queen's General Hospital program in New York completing his residency in 1946.

He returned to Hartford to practice surgery and affiliated with the Mt. Sinai Hospital in Hartford and the McCook Memorial Hospital. Over the years, he rose to attending surgeon at Mt. Sinai Hospital and served as Secretary of its staff. At McCook Memorial Hospital, he became one of four surgical chiefs prior to the University of Connecticut's assuming control of the hospital.

Dr. Beizer was a fellow of the American College of Surgeons and of the International College of Surgeons, and a member of the American Board of Abdominal Surgeons. He was also a member of Hartford Medical Society, Hartford County Medical Association, and Connecticut State Medical Society.

"Young Ed", as he was known, maintained a youthful appearance and attitude at all times. Always curious and searching for more information, he was a devoted adherent to continuing medical education so that he could incorporate the best of his medical knowledge and information to his delivery of health care. He was always friendly, compassionate, responsible, and devoted to his patients. He came second.

He is survived by his widow, the former Maxine Kolodney; two sons, Bob and Rick (both lawyers); and two grandchildren. Dr. Beizer derived much pleasure from his family watching his two sons rise in the legal profession after having successful athletic careers at Yale and Harvard. It was on his return from a visit to Washington, D.C. to his family that he was seized with a myocardial infarction leaving his family, friends, and patients pleasant memories of a devoted, loyal, humane servant to all people.

Charles Polivy, M.D.

In Memoriam

Allen, Edward P., Yale Medical School, 1924. Dr. Allen was a surgeon in the New Haven area since 1924. He received his M.D. from Yale University in 1924 and earned his board during those years by working in the laboratories of St. Raphael's Hospital. Upon his graduation he became a member of the hospital's staff and serves as president of the staff at St. Raphael's from 1957 to 1958. Dr. Allen was greatly interested in cancer and published several medical papers on the subject. He was a member of the Medical Society of the City of New Haven, the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Allen died November 23, 1976, at the age of 82.

Brosnan, John F., Tufts Medical College, 1930. Dr. Brosnan was a urologist in the New London area since 1931. He was a former chief of urology at Lawrence Memorial Hospital where he was a member of the staff for 46 years. He was appointed chief of urology in 1959 and remained in that post until he transferred to the hospital's consulting staff in 1975. He was a member of the New London County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Brosnan died November 22, 1976, at the age of 71.

Finn, Alfred J., Bowdoin Medical School, 1921. Dr. Finn was a former police and fire department surgeon and a practicing physician for more than 50 years in the New Haven area. He was a World War I veteran and served in the U.S. Army. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Finn died September 29, 1976, at the age of 83.

Fitzpatrick, Wesley F., Cornell University Medical College, 1938. Dr. Fitzpatrick was the first resident intern at Norwalk Hospital. Prior to coming to Norwalk he worked as a bacteriologist and chemist at the Rockefeller Institute, New York City. His research there was related to yellow fever. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Fitzpatrick died October 18, 1976, at the age of 72.

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiry of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511, (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine*.

PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

Pediatrics (Allergy) Available July 1977. Board certified. Interested in teaching and affiliation with group or associate type practice or institutional position. 31 years old. Presently in service. M.D. from Jefferson. Residency at New York Hospital. Fellowship at University of Colorado. Michael Z. Blumberg, M.D., 701 North Lincoln Street, O'Fallon, IL 62269.

Pediatrics: Board eligible. Presently on active duty. Available August 1977. Bowdoin graduate. M.D. from Duke. Residency at Children's Hospital in Pittsburgh. 30 years old. Neal G. Bornstein, M.D., 89 Totten Street, Ft. Leonard Wood, MO 65473.

Pediatrics: Board eligible. Completing tour of duty with the Navy. Available July 1977. Amherst graduate. M.D. from S.U.N.Y. Downstate. Residency at Roosevelt Hospital in NYC. Desires group practice. Wife completing Ph.D. Would desire teaching opportunity. Ronald S. Bashian, M.D., 2521 South Meridian Dr., Great Lakes, IL 60088.

Pediatrics: Board eligible. Available July 1977. Undergraduate degree and M.D. from B.U. Residency at Cincinnati Children's Hospital. Special interest in learning disabilities. Robert W. Chamberlain, M.D., 4960 Hawaiian Terrace, Cincinnati, OH 45223.

Pediatrics: Board certified. 31 years old. Desires group or institutional position. Presently on active duty. Brown graduate. M.D. from NYU. Chief resident at Bronx Municipal Medical Center. Edward B. Charney, M.D., 128-1 Kirkbridge Road, Voorhees, NJ 08043.

Pediatrics (Nephrology) Some general pediatrics with pediatric and adult nephrology. Board certified. Available summer of 1977. Desires group practice. Graduate of University of Penn. M.D. from Marquette College of Medicine. Residency at Univ. of Michigan. 32 years old. Francis DiBona, M.D., 265 Park Lane, Ann Arbor, MI 48103

Pediatrics: Board eligible. Completing training at R.I. Hospital. M.D. from Tufts. Solo, group or associate practice will be considered. 28 years old. Available July 1977. Alfred Dushman, M.D., 3595 Post Road, Apt. 13-301, Warwick, RI 02886.

Pediatrics: Available July 1977. Board eligible. 28 years old. Graduate of Univ. of Rochester. M.D. from Meharry Medical. Completing training at R.I. Hospital-Brown University. Desires group or associate practice. Richard L. Dvorin, M.D., 73 Keene Street, Providence, RI 02906.

Pediatrics: Board eligible. Available summer of 1977. Now on active duty. Holy Cross graduate. M.D. from Vermont. Residency at University of Colorado Medical Center. Group or associate practice. Donald L. McGuirk, Jr., M.D., 6793 Seversky Drive, Edwards, CA 93523.

Pediatrics (Behavioral Problems) Available July 1977. 32 years old. Complete Behavioral Fellowship at University of Virginia. Columbia graduate. M.D. from S.U.N.Y. at Buffalo. Desires solo, group or associate practice. Wishes general pediatrics with

subspecialty opportunities. Board certified. Stephen Schlesinger, M.D., 2309 Tarleton Dr., Charlottesville, VA 22901.

Pediatrics: Board eligible. Connecticut license pending. Available spring of 1977. 40 years old. Wishes to relocate in Connecticut. Institutional or public health position desires. R. Marc Schwartz, M.D., 270 Point of Woods Dr., Portage, MI 49081.

Pediatrics: Board eligible. Available July 1977. Special interest in Fairfield County. M.D. from Medical College of Virginia. Completing training at North Shore Univ. Hospital in Manhasset, L.I. 27 years old. Robert A. Shanik, M.D., 8 Wooley Lane, Apt. B24, Great Neck, NY 11023.

Pediatrics: Board certified. Desires solo practice in small community. 32 years old. Presently in practice and wishes to relocate to the East coast. M.D. from McGill. Undergraduate work at Johns Hopkins. Residency at Mayo Clinic. Resume on file at CSMS. T.H.W.—Ped.

Physical Medicine: Available July 1977. Board eligible. FLEX. Presently in practice on Long Island. Trained at Mt. Sinai in NYC. M. Focseneanu, M.D., 66-36 Yellowstone Blvd., Apt. 15G., Forest Hills, NY 11375.

Psychiatry: Presently available for part time appointment along with present private practice. Connecticut license. Fairfield County area desired. Clinic setting, out patient and/or consultations. Colin B. Cook, M.D., 297 High Ridge Road, Stamford, CT 06905.

Radiology: Seeking directorship of a Department of Radiology in a small or medium sized hospital. Experienced in all aspects of diagnostic radiology, including nuclear medicine, angiography and ultrasound. Board certified. 40 years old. Arthur J. Day, M.D., 58 Saddleback Road, Rolling Hills, CA 90274.

Radiology (Diagnostic) Board certified. 30 years old. Married to a surgeon. Available July 1977. Group or associate practice. M.D. from NYU. Advanced training at Emory and NYU. Phyllis R. Jarvis, M.D., 5116 Professional Drive, #88, Wichita Falls, TX 76302.

Radiology: Board certified. 28 years old. M.D. from SUNY in Buffalo. Trained at Cornell. Presently Director of Department of Radiology, Norristown State Hospital. R. Scott Scheer, M.D., Heritage Lane, Valley Forge, PA 19481.

Radiology: Connecticut license. Board eligible. M.D. from L.S.U. in New Orleans. Residency at New York Hospital. Presently at St. Elizabeth Hospital in Elizabeth, N.J. Wishes to relocate in Conn. Genevieve Wellbaum, M.D., 945 Woodland Ave., Plainfield, N J 07060.

Anesthesiology: Wishes to relocate in the U.S.A. Connecticut license pending. Trained in Ireland and Canada. Certified in Canada. 47 years of age. Married. Medium sized community desired. Roy B. Weston, M.D., 7 Warlock Crescent, Willowdale, Ontario, Canada.

Industrial or Institutional Medicine: Part time or full time. Desires western Connecticut within fifty mile radius of Hudson Valley area in New York State. 64 years old. Experience in family practice and general surgery. Vincent V. Barone, M.D., Charlotte Road, Fishkill, N.Y.

Internal Medicine: Board eligible. Available July 1977. Desires Southwestern Connecticut. M.D. from Emory; Internship and residence at Tulane. 28 years old. Married. Group or associate practice. General medicine. Bennett H. Bruckner, M.D., 3915 St. Charles Avenue, New Orleans, LA 70115.

Obs/Gyn: Available in July. Connecticut license. Presently at Yale New Haven Health Center. Had been Coordinator of Obstetrics USPHS. Indian Hospital. Columbia undergraduate; M.D. from NYU. 30 years old. Married. Desires large or medium sized community. Ian M. Cohen, M.D., 182 Ray Road, New Haven, CT 06515. Telephone 389-9879.



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Obs/Gyn: Available July 1977. Connecticut license through FLEX. Presently at UConn Health Center. M.D. from Wayne State in Michigan. Fellowship at Harvard. 32 years old. Kenneth J. Hekman, M.D., 62 West End Avenue, New Britain, CT 06052.

Obs/Gyn: Board eligible. Available July 1977. Completing residency at Washington University/Barnes Hospital. Desires group or associate practice. 29 years old. Charles T. Mann, M.D., 11 Lauder Court, Creve Coeur, MO 63131.

Obs/Gyn: Available now. Desires Greater New Haven area. Connecticut license. Clinic position. Experience with Family Planning Nurse Practitioners. Armada M. Sittig, M.D., 587C Prospect Street, New Haven, CT 06511 (776-4318).

Ophthalmology: Available November 1977. Board eligible. Dartmouth Graduate; M.D. from University of Pennsylvania; Internship at Greenwich Hospital; University of Penn. residency. Presently on active duty. 31 years old. Married. Solo, group or associate practice. Jay B. Gooze, M.D., 556OA Hiers Street, Ft. Knox, KY 40121.

Ophthalmology: M.D. from Einstein College of Medicine; solo, group or associate practice. Available summer of 1977. 33 years old. Board eligible. Special interest in retinal diseases and fluoroscein

angiography and photocoagulation. Sterling J. Haidt, M.D., 737 El Medio Avenue, Pacific Palisades, CA 90272.

Ophthalmology: Available July 1977. M.D. from St. Louis University. Completing residency at Ohio State University Hospital. Board eligible. Solo, group associate practice. George R. Zambelli, M.D., 1353 Bradshire Road, Columbus, O 43220.

Orthopaedic Surgery: Available July 1977. Board eligible. Sat for exams in September. Completing residency at Duke University Medical Center. 33 years old. Desires group, associate or institutional practice. Dartmouth graduate. M.D. from Duke. Resume on file at CSMS. P.K.K. Ortho.

Orthopaedic Surgery: Available July 1977. 30 years old. Completing residency at University of Michigan. M.D. from Northwestern University. Desires group practice. Thomas J. O'Keefe, M.D., 655 Hidden Valley Drive, Ann Arbor MI 48104.

ENT: Available July 1977. Board eligible. M.D. from Georgetown. Residency at Washington Hospital Center. Desires coastal area. Solo, group or associate practice. Arthur H. Schwartz, M.D., 2517K N.W. #601, Washington, D.C. Telephone 202-337-5625.

Pathology: Anatomic and Clinical. Available May 1977. Board certified. Presently on active duty with US Navy. M.D. from Temple. Internship and residency at the Naval Hospital in Oakland, California, Thomas J. Joseph, M.D., 46 Brighton Drive, Gaithersburg, MD 20760.

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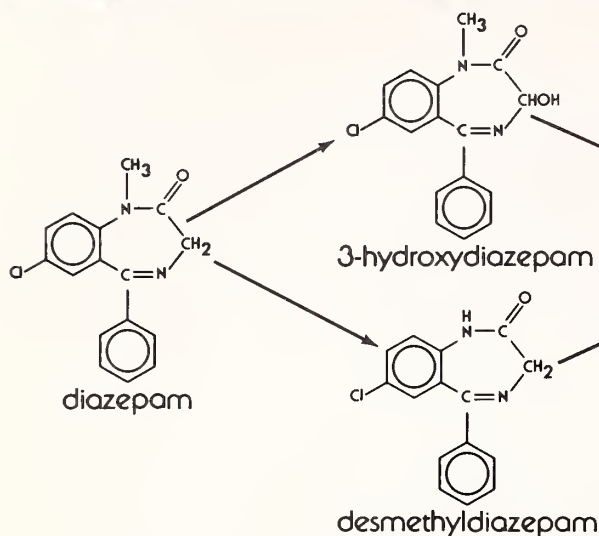
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Bilateral Adrenalectomy for Advanced Female Breast Cancer

N. William Wawro, M.D., M.J. Mukerji, M.D. and Michael Deren, M.D.

ABSTRACT—A retrospective analysis of 109 bilateral adrenalectomies at the Hartford Hospital for advanced female breast cancer in this period of 1960 to 1973 revealed an objective response rate of 42% for six months or longer. Ten responding patients survived more than two years.

The most significant variables affecting response

rate are age of patient, duration of the free interval, endocrine dependence and the site of metastatic spread.

All pre-menopausal females to respond to oophorectomy in our series, failed to respond to adrenalectomy.

Introduction

While it is recognized that recurrent or advanced female breast cancer is uniformly fatal, its behavior is that of a chronic disease. By careful manipulation of the several available treatment modalities, i.e., radiation therapy, additive and/or ablative hormone therapy and chemotherapy, survival time can be prolonged and quality of life improved.

Taking advantage of the demonstrated palliation in advanced female breast cancer achieved by oophorectomy,¹ hypophysectomy² and adrenalectomy,³ a cooperative study from thirteen institutions compared the palliative benefits of adrenalectomy versus hypophysectomy. The findings of the Joint Committee on Endocrine Ablative Procedure and Disseminated Mammary Cancer released in 1962 revealed an essentially similar success rate (32%) in a group of 801 adrenalectomies, compared with 390 hypophysectomies.⁴ This study also revealed that objective improvement was most commonly noted in those patients who had a long "free interval" between their initial mastectomy and recurrence of disease, presenting with dominant soft tissue and/or skeletal metastases, and whose breast neoplasm demonstrated endocrine dependence through regression induced by previous hormone additive therapy or palliative oophorectomy.

Thus it is clear that breast cancer regression and temporary control can be achieved by removing the trophic stimulus originating from the pituitary-adrenal-ovarian axis.

More recently biochemical means have been investigated to more precisely predict endocrine dependence, that is, the estradiol cytoplasmic-binding receptor,⁵ prolactin suppression by Levodopa,⁶ and urinary steroid assay. Despite these clinical and biochemical guides to endocrine dependence or auton-

omy, there are responders who violate these parameters. Patients with no free interval, others with no prior response to endocrine manipulation and some with visceral metastases have demonstrated objective remission following adrenalectomy.^{8,9}

However, the evidence for substantial palliation by adrenalectomy in advanced breast cancer clearly favors patients who are elderly, with a significant free interval (three years or more), with metastases in dominantly "low risk" sites, i.e., soft tissue and bone, and demonstrable endocrine dependence. Such over-selection can yield an objective response rate of 60% following adrenalectomy.^{10,11} Our experience generally confirms these conclusions.

Material

In the period of 1960-1973, one hundred and nine patients had bilateral adrenalectomies at the Hartford Hospital for advanced metastatic female breast cancer. Excluded from this retrospective review were patients with extensive metastatic visceral disease, particularly to liver, pleuro-pulmonary and central nervous systems. Other medical contraindications to such surgery were incompetent cardiovascular systems, cerebral deterioration, advanced age and debility.

Criteria for an objective response to adrenalectomy were measurable partial or total regression of soft tissue disease, healing of all or most of the lytic skeletal metastases, total or partial clearance of pulmonary lesions, failure of hydrothorax to reaccumulate and absence of new lesions, sustained for a minimum of six months.

Methods

The bilateral twelfth rib resection in the lumbar prone position was used in the majority of patients for adrenalectomy in this group. This was synchronously preceded by bilateral oophorectomy utilizing the separate lower abdominal midline incision, when ovaries were present.

DR. N. WILLIAM WAWRO, Department of Surgery; DR. M.J. MUKERJI, Resident Department of Surgery; DR. MICHAEL DEREN, Resident, Department of Surgery; all of the Hartford Hospital.

Excluded from this report are three patients with sufficient metastases to the adrenal glands and fixation to the surrounding structures precluding removal.

Thirty-two patients had microscopic adrenal gland metastasis insufficient to prevent resection.

Results

Forty-five of the one hundred and nine patients experienced an objective remission for six months or longer (42%) following bilateral adrenalectomy for advanced breast cancer at the Hartford Hospital. A cumulative group 1008 patients from six other separate series yielded a response rate of 44%⁹ following bilateral adrenalectomy for advanced breast cancer. Our experience matches these reports.

The average duration of adrenalectomy remission among the responders was eighteen months and the average survival of this category was twenty-six months. In contrast, the average survival period of the non-responders was but eight months.

In a sub-group of twelve women, who presented with advanced breast cancer without previous treatment, classified as the "no free interval" group, nine demonstrated a remission of at least six months after adrenalectomy.

Similarly, another category that deserves careful scrutiny, consists of ten patients whose favorable response after adrenalectomy exceeded two years and was maintained up to seven years. A profile analysis of these women reveal that eight of these ten were postmenopausal, with long free intervals and a metastatic pattern of dominant soft tissue and skeletal involvement.

It was noted that responding patients had a shorter median hospitalization of twelve days in contrast to the average stay of sixteen days for non-responders.

Eight patients died within thirty days of surgery (7%), five from respiratory failure, two from hepatic dysfunction and one from central nervous system coma.

Major complications were noted in sixteen patients (15%), principally related to cardiopulmonary problems and wound infection.

Discussion

The natural history of female breast cancer is varied with impressive differences in behavior, particularly in the pre- and post-menopausal age groups.

Two-thirds of our responders were post-menopausal with a median age of fifty-three years of age. Similarly, the responding group had an average free interval between initial mastectomy and subsequent metastases of sixty-one months, in contrast

with a shorter average free interval of thirty-one months in the group which failed to respond. (Table I)

Endocrine "dependence" was measured by favorable response to either a previous oophorectomy in the pre-menopausal woman, or a favorable response to

TABLE I
BILATERAL ADRENALECTOMY
HARTFORD HOSPITAL
1960 - 1973

ADRENALECTOMY RESPONSE RELATED TO FREE INTERVAL AND AGE OF PATIENT

	AGE OF PATIENT	FREE INTERVAL
RESPONDERS	53 (31-74 YRS.)	61 MOS. (10 MOS.-168 MOS.)
NON-RESPONDERS	50 (28-72 YRS.)	31 MOS. (1 MO. - 108 MOS.)

preoperative estrogens or androgens in the post-menopausal group. Forty pre-menopausal women had a therapeutic oophorectomy when advanced breast cancer was noted. Eighteen of these responded; thirteen of this group of eighteen "endocrine dependent" women responded to subsequent adrenalectomy. (Table II)

TABLE II
BILATERAL ADRENALECTOMY
HARTFORD HOSPITAL
1960 - 1973

ADRENALECTOMY RESPONSE RELATED TO OOPHORECTOMY RESPONSE

	RESPONDERS	NON-RESPONDERS
18 OOPHORECTOMY RESPONDERS	13	5*

*5 PREMENOPAUSAL RESPONDERS TO OOPHORECTOMY FAILED TO RESPOND TO ADRENALECTOMY (3 LIVER, 1 CNS & ASCITES, 1 PLEURA-ASCITES-BONE)

Consonant with this pattern, the majority of post-menopausal patients who had a clear response to additive hormone therapy utilizing stilbestrol or androgens also enjoyed a subsequent remission after adrenalectomy.

Pre-menopausal women who did not respond to therapeutic oophorectomy in our series also failed to respond to adrenalectomy. However, this experience is not supported in other series;^{12, 13} 15-25% of pre-menopausal patients demonstrating no response to previous oophorectomy have enjoyed a remission following adrenalectomy.

In assessing the relationship between metastatic sites and adrenalectomy response, it is clear from our study and confirmed by others that the response rate and length of remission are best in those patients with dominant soft tissue and/or bony metastases, while the response is minimal in patients presenting with visceral, liver and lymphangitic pulmonary disease.

(Table III). In further support of this, a profile of the ten women in our series who responded for longer than two years after adrenalectomy reveals that the majority had soft tissue and skeletal disease, although two also had some peritoneal and pleural-pulmonary nodular disease.

TABLE III
BILATERAL ADRENALECTOMY
HARTFORD HOSPITAL
1960 - 1973

ADRENALECTOMY RESPONSE RELATED TO MAJOR SITE OF METASTASES

BONE	28/46	60%
SOFT TISSUE	22/41	53%
PLEURA & LUNG	12/40	30%
VISCERAL	10/36	28%

In general, bilateral lymphangitic pulmonary metastases, extensive liver involvement and central-nervous system spread are contraindications for adrenalectomy. On the other hand, minimal pleural-pulmonary, liver and peritoneal involvement have been associated with a significant response.

In this retrospective evaluation, we did not use biochemical methods to evaluate tumor dependence, i.e., by utilizing Levodopa for prolactin suppression, measuring estradiol receptor activity in the breast tumor or determining the output of urinary steroids. We have relied upon the multiple clinical variables described above as guides for understanding the disease dynamics and predicting response to adrenalectomy.

Thus, from current available data and experience it is clear that the post-menopausal woman with a free interval of three years or longer, demonstrating prior beneficial response to endocrine manipulation and presenting with soft tissue and/or skeletal metastatic breast cancer, should expect an objective remission rate of about 65% following bilateral adrenalectomy. (Table IV).

One must caution that such over-selection, however, will deny a small but significant percentage of women objective palliation. It has been observed in this series and others that pre- and post-menopausal women with advanced locally inoperable and metastatic breast cancer, the so called "no free interval" group, may respond to bilateral adrenalectomy as the primary treatment.

A careful assessment of all these clinical factors is essential prior to offering adrenalectomy to the pa-

TABLE IV
BILATERAL ADRENALECTOMY
HARTFORD HOSPITAL
1960 - 1973

PROGNOSTIC VARIABLES IN ADRENALECTOMY

VARIABLES	FAVORABLE	UNFAVORABLE
AGE	POSTMENOPAUSAL	PREMENOPAUSAL
FREE * INTERVAL	3 YRS. AND LONGER	0** - 2½ YRS
ENDOCRINE STATUS	DEPENDENT	AUTONOMOUS
METASTASES	SKIN SOFT TISSUE BONE	CENTRAL NERVOUS SYSTEM LIVER LUNG

* TIME FROM MASTECTOMY TO RECURRENCE

**NO TIME INTERVAL GROUP MUST BE INDIVIDUALLY ASSESSED

tient. The mortality and morbidity must be weighed against the expected remission rate. Further, it is well to remember that such modification of hormonal balance results in only transient growth restraint and control. Inevitably, cancer will recur and continue its fatal course.

Hypoadrenalism (Addisonian state) has not been a rehabilitation problem since the patients and their families are instructed in the management of this deficiency state. Under basal conditions, a daily oral dose of 37½-50 mg. of cortisone acetate is sufficient to maintain homeostasis, adding the mineral corticoid fluorineff (0.1 mgm.) on alternate days. Supplemental enteric coated salt is used as needed varying with climactic conditions. In a stress state, all doses are increased and the route of administration may be changed. On this replacement program, patients have resumed their former occupations while in remission.

There are proponents¹⁴ for an immediate and adjunctive use of the technique of simultaneous oophorectomy and adrenalectomy in advanced breast cancer on the supposition that altering the hormonal milieu synchronously with the radical mastectomy, when the host tumor burden is presumably minimal, yields prolonged survival. Such an approach eliminates selection based on the clinical and biochemical variables described above. This approach was not employed in this series.

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Intra-Cranial Complications of Sinusitis

Agnes Yue, M.D. and Clarence T. Sasaki, M.D.

ABSTRACT—Intracranial complications of sinusitis may produce devastating neurologic sequelae or even death. Delay in diagnosis may result from partial or inadequate treatment of sinusitis. Eight such complications were treated at the Yale-New Haven Hospital over the past five years. Five of these cases involved

the frontal sinus as the untreated source of intracranial infection. The causative organism in five of eight complications was a variety of streptococcus. Prompt and adequate treatment of sinusitis is emphasized in the prevention of life-threatening intracranial complications.

Introduction

Intracranial complications of sinusitis, although uncommon today, may result in devastating neurologic sequelae or even death. The mortality rate has decreased from 100% in the preantibiotic era to approximately 40% today.^{1,3} Needless to say, antibiotics have drastically altered the course of bacterial infections of the upper respiratory tract. Despite such medical advances, life-threatening complications of sinus disease will occasionally baffle and elude the most sophisticated contemporary diagnostician. While misdiagnosis may result from the overall scarcity of bacterial complications today, it is more often due to partial or inadequate treatment of acute sinusitis.

Richter⁴ in 1773 described the first case of extradural and subdural empyema from chronic frontal sinusitis in a 50 year old man who developed hemiparesis and aphasia. From a historical perspective in this regard, intracranial complications of sinusitis most frequently resulted from acute frontal sinusitis

or exacerbations of chronic frontal disease.⁵ On the other hand, extension from maxillary, ethmoid and sphenoid sinuses were rarely recorded. Unexplainably in this regard the incidence of complications seemed to be higher in males than females by a ratio of 4 to 1.⁶

A review of our experience during the last five years correlates well with this incidence and again confirms the frontal sinus as the primary source of intracranial complications. (Table I) On the other hand, ethmoid sinusitis will more often produce orbital complications before intracranial involvement may result. Maxillary sinusitis rarely involves vital organs because of its distance from them. Acute sphenoid sinusitis is rare but could produce cavernous sinus thrombosis by virtue of its anatomic proximity to it.⁷

With regard to the frontal sinus, specific anatomic considerations contribute to the pathogenesis of infectious spread intracranially. The bone separating the frontal sinus from the cranial cavity is thin, allowing an osteomyelitic process to extend contiguously to the epidural space. Direct extension may also occur by pathways of least resistance across sites of previous trauma or fracture to cause involvement epidurally. Extradural involvement may also result from hematogenous spread of infection across communicating

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Table 1
INTRACRANIAL COMPLICATIONS OF SINUSITIS
YALE-NEW HAVEN HOSPITAL

	<i>Patient</i>	<i>Sex</i>	<i>Age</i>	<i>Sinus</i>	<i>Complication</i>	<i>Organism</i>
1.	CM	M	30	Frontal	Epidural Abscess	Anaerobic Streptococcus
2.	RP	M	13	Frontal	Subdural Abscess	B streptococcus Group A
3.	DM	M	18	Frontal	Subdural Abscess	Streptococcus Viridans
4.	DA	M	38	Frontal	Brain Abscess	Anaerobic streptococcus
5.	WH	M	27	Frontal	Meningitis	Hemophilus influenza
6.	DM	M	5	Maxillary	Meningitis	Hemophilus influenza
7.	CM	F	78	Maxillary	Meningitis	Negative culture - on penicillin
8.	AW	F	18	Sphenoid	Brain Abscess	Anaerobic streptococcus

veins to the dural sinuses. The subdural and subarachnoid spaces may be further involved in a retrograde direction across the cerebral cortical veins. Because these veins lack valves, flow through them may be easily reversed by any thrombophlebitic process. By such mechanisms, therefore, intracranial complications of frontal sinusitis may potentially include epidural and subdural abscesses, septic thrombosis of the cavernous or superior sagittal sinuses, meningitis or brain abscess.

The organisms most commonly isolated in subdural and epidural empyemas secondary to sinusitis are streptococcus pyogenes and viridans^{5, 8} although anaerobic streptococcus may occasionally be the causative organism. Staphylococcus, pneumococcus and hemophilus, although common to acute sinusitis, are less commonly etiologic agents in the extension of disease beyond the confines of the paranasal sinuses.

Illustrative Case Reports

Case number one (1) was a 13 year old right handed boy who was well until ten days prior to admission, when he developed a fever of 99.8° F, generalized malaise, and symptoms of "the flu" for which he received antihistamine, decongestant medication. He had developed nausea and intermittent vomiting several days prior to admission. On the morning of hospitalization, the boy allegedly fell in the bathroom and had a generalized seizure. On admission he was noted to have ongoing focal seizures, a left hemiparesis, and marked meningismus. His temperature was 100.4°F and his white count was 7500.

An electroencephalogram revealed right parietal spike focus. A brain scan showed increased uptake in the right temple and occiput. Skull x-rays were normal. A lumbar puncture revealed increased pressure with mild leukocytosis. No bacteria were seen by microscopic examination of the cerebrospinal fluid. The patient was placed on dexamethazone (Decadron), phenobarbital, and diphe-

nylhydantoin (Dilantin). However, his condition continued to deteriorate with decreasing levels of consciousness and more frequent focal seizures. Because the patient was thought to have viral encephalitis with an expanding subdural effusion, neurosurgical consultation was eventually sought 48 hours after his admission

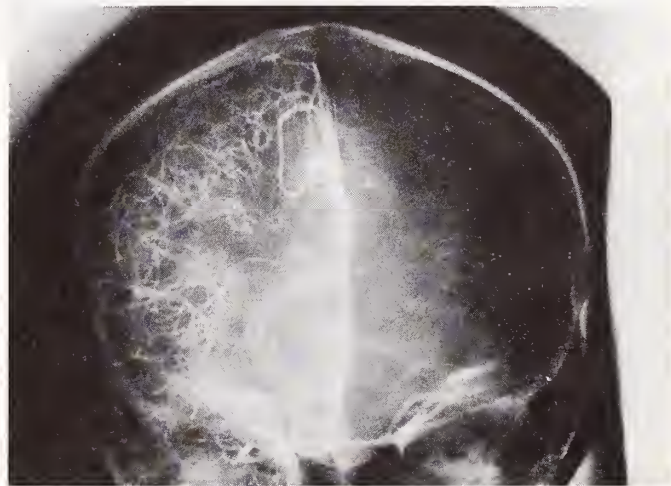


Figure 1

Right carotid angiogram demonstrating an avascular zone over the parietal convexity.

and a right carotid angiogram was obtained to show a small avascular zone over the right parietal convexity. (Figure 1) On the second hospital day, the patient was thus taken to the operating room, where a large amount of subdural pus totaling 100 ccs. was evacuated by means of multiple burr holes. However, review of the patient's postoperative X-rays (Figure 2) showed clouding in both frontal and maxillary sinuses prompting an otolaryngologic consultation. Under a second general anesthetic, the right frontal sinus was trephined and a large amount of purulent material aspirated from it. Beta streptococcus group A, was cultured from this aspirate, the same organism having been obtained from the subdural space. Daily frontal sinus irrigations were performed through the external trephination. The patient now began a rapid improvement and he was discharged on the



Figure 2

Clouding of the right frontal sinus.



Figure 3

Patchy osteomyelitis of the frontal bone.

20th hospital day with essentially no residual neurologic deficits except for a mild paresis of the left upper extremity.

Case number two (2) was a 30 year old right handed man who complained of recurrent frontal headaches. One day he was found in his living room unconscious with decerebrate posturing. His family stated he had suffered from recurrent sinusitis and had complained of intermittent occipito-frontal right-sided headaches for two weeks prior to his hospital admission. He also had developed nausea and vomiting for four days preceding his emergency admission. He had in fact been seen weeks ago by his family physician who diagnosed pansinusitis and had recommended tetracycline for treatment of this infection.

On admission, skull X-rays showed right frontal osteomyelitis. (Figure 3) Laminograms of the frontal sinus confirmed a dehiscence posterior wall and mucosal thickening suggestive of chronic sinus inflammation. On the second hospital day, a carotid angiogram revealed bifrontal epidural collections. (Figure 4)

The patient continued to deteriorate with increasing focal seizures. He underwent a bifrontal craniectomy exposing a large epidural abscess totaling 200 ccs. Because of the extensive osteomyelitis, the frontal sinus was surgically ablated. Cultures of epidural pus produced anaerobic streptococcus. Marked neurologic improvement now resulted and the patient was discharged on the 12th hospital day on oral antibiotics.

Comments

Rhinogenic intracranial complications are rare but potentially life-threatening. This is grossly evident from a review of our experience as well as those of

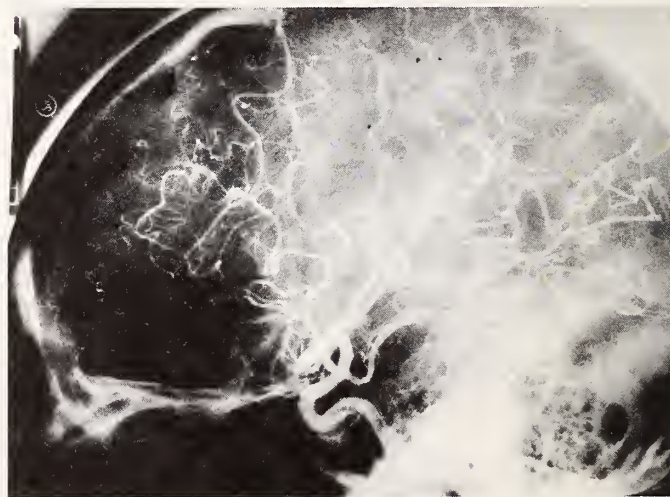


Figure 4

Carotid angiogram demonstrating a large avascular zone over the frontal convexity.

others.^{2, 3, 8} Delayed diagnosis often results from partial treatment of sinus disease rather than a disregard of patient symptoms. On the other hand, the frontal lobe, which is most often involved, is a relatively silent area of the brain and early changes in a patient's judgement and behavior may go unnoticed by even his close relatives.

Pitfalls in diagnosis may be related to other non-specific symptoms. Certainly headache is common to both sinus disease and intracranial lesions and may therefore be difficult to assess. Vomiting consistent with increasing intracranial pressure on the other hand, is of great significance and should stimulate further neurologic investigation. Drowsiness and meningismus may be late signs of progressive intracranial extension and should involve the early efforts of the neurosurgical team.

Prevention of such complications should necessarily involve the otolaryngologist, when acute infections fail to resolve or are recurrent despite appropriate antibiotics and decongestants. In this regard, headache, fever, and malaise are nonspecific symptoms of sinus infection. However, persistent purulent postnasal discharge and localized pain should suggest ongoing sinusitis. Although sinus transillumination may be helpful, sinus X-rays are the only definitive method of diagnosis at this stage of evaluation. When symptoms persist beyond three weeks despite adequate conservative therapy, an otolaryngologist's services should therefore be advised. Minor intranasal procedures such as sinus irrigations, polypectomies, and partial turbinectomies may adequately reverse the inflammatory process by improving sinus aeration and drain-

age. However, should such conservative surgical measures fail to reverse mucosal disease, more radical maneuvers may be necessary to permanently exenterate, ablate or obliterate the infected sinus mucosae.

Intracranial complications of sinusitis are potentially life-threatening and by no means represent diagnoses of the historical past.

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Acute Respiratory Failure in the Surgical Patient

Paul G. Barash, M.D. and Boonsri Kosarussavadi, M.D.

It has been estimated that 70-90% of admissions to the intensive care units (ICU) for patients with acute respiratory failure (other than those involving exacerbation of chronic obstructive pulmonary disease) are from the surgical service. Pre-operatively, if the lung volume (the vital capacity) is reduced by 50% and the pulmonary mechanics (the forced vital capacity) is reduced to 50%, there is a 50% chance of developing acute respiratory failure following upper abdominal surgery. This carries a 20% of mortality.¹ Thus, it is incumbent on those who are involved in the management of surgical patients to recognize the population at risk so that these complications can be minimized.

Numerous factors have been associated with an increased risk of pulmonary complications following surgery. According to Bendixen² pre-operative abnormal lung function carries the highest risk for post-operative atelectasis or pneumonia. In reviewing the literature involving pulmonary complications in sur-

gical patients certain other risk factors have become evident:² a) increased incidence with upper abdominal or thoracic surgery, b) increased frequency and severity as duration of surgery and anesthesia increases and c) higher incidence in those with pre-existing pulmonary disease, obesity or advanced age. Appropriate pre-operative preparation reduced post-operative complications.

Initially, the history and physical examination are extremely important in determining the population at risk. In addition to routine admission laboratory data (including chest x-ray and electrocardiogram) arterial blood gas analysis should be performed. It represents an integration of the entire respiratory process. In a healthy man, the arterial oxygen tension (PaO₂) decreases with age.³ Thus, at age 21, a normal PaO₂ is 95 mmHg whereas at age 70, it is approximately 75 mmHg. In those people whose blood gas values are not appropriate to their clinical situation, pulmonary function tests are requested. Two indications for ordering these tests are: 1) further diagnostic evaluation and 2) as a pre-operative baseline.

These patients are then managed according to their major problems. For example, acute respiratory in-

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fection should be treated and surgery delayed until full recovery. Obese patients are placed on the appropriate diet. Smokers are encouraged to discontinue their habit. Patients with chronic productive cough receive postural drainage, breathing exercises and intermittent positive pressure breathing (IPPB) pre-operatively (3-7 days) to improve pulmonary function. Surgery is scheduled as the second or third case in the morning so they can ambulate and expectorate their secretions prior to operation.

In one representative series,⁴ it was shown that if chest physiotherapy (PT) was utilized both pre-operatively and post-operatively, there was a 12% incidence of atelectasis and pneumonia following cholecystectomy. This rose to 27% if PT was used only after surgery and 41% if no pulmonary toilet was given to the patient. It is also important to maximize the educational value of IPPB and postural drainage.

In the operating room, extensive monitoring is utilized if the surgical procedure or the patient's physical status warrants. In addition to blood pressure, pulse, EKG, temperature, intake and output, an indwelling arterial catheter and a pulmonary artery flow guided catheter (Swan-Ganz®)⁵ are commonly used. We have found these extremely useful in monitoring the patient's respiratory and cardiovascular response to the stress of surgery and anesthesia.⁶ During surgery, in the supine position for example, the functional residual capacity (resting lung volume) decreases and causes alveolar collapse, airway closure and gas trapping. Compliance decreases and the "stiff lung" can develop. As a result, an intra-pulmonary shunt develops. A similar mechanism occurs in patients with post-traumatic pulmonary insufficiency. The operation and the operative site have much to do with the development of pulmonary complications. Using vital capacity as a measure of pulmonary reserve, it has been shown that there is virtually no loss in vital capacity with peripheral or non-abdominal procedures. Patients who undergo a herniorrhaphy or an appendectomy can lose 50% of their pulmonary reserve post-operatively and it may take as long as 10 days to regain the preoperative vital capacity. Further, patients undergoing a cholecystectomy can have a 75% decrease of their pulmonary reserve following surgery.⁷

In the immediate post-operative period, patients can have significant hypoxemia for as long as 2 or 3 days post-operatively.⁸ Thus, elderly patients who have decreased arterial oxygen tension initially can rapidly become hypoxemic. It has been hypothesized that one of the possible reasons for post-operative myocardial infarction is this hypoxemia.⁹ Following thoracic and abdominal surgery, wound pain can prevent the patient from sighing and effectively coughing.

Post-operative narcotic analgesia can also cause iatrogenic problems. Morphine not only decreases the respiratory rate, but can abolish the sigh mechanism and alter the response to carbon dioxide. With hypoventilation and inability to take intermittent deep breaths, the patient is further prone to atelectasis.

Despite the vigorous attempts to define and treat the population at risk, there are situations where we cannot improve the patient's pulmonary status i.e. emergency surgery or patients who are refractory to treatment. Patients from this group are especially prone to post-operative respiratory insufficiency. The clinical manifestations of acute respiratory failure are those basically of hypoxemia. Central nervous system manifestations include: anxiety, restlessness, headache, somnolence and finally coma. Respiratory manifestations include: tachypnea, shallow respiration and finally cyanosis. Myocardial hypoxemia causes bradycardia or tachyarrhythmias, hypotension and congestive heart failure. The syndrome of acute respiratory failure is that of dyspnea, tachypnea, decreased pulmonary compliance ("stiff lung") hypotension and cyanosis. The four basic causes of hypoxemia are:¹⁰ 1) hypoventilation (diagnosed by P_aCO_2), 2) diffusion defect (this is rarely the major cause of hypoxemia), 3) ventilation perfusion abnormality and 4) pure atelectasis.

The rational of therapy should involve: 1) treating the underlying pathology, 2) preventing further alveolar collapse, 3) maintaining adequate oxygenation and ventilation and 4) preventing and treating infection. The respirator management should achieve as ideal a ventilatory pattern as possible which maximizes the efficiency of gas exchange. The ventilatory pattern¹¹ should a) be as harmless as possible to all structures of the lung, b) allow the acute injury to heal itself, c) cause no important changes in hemodynamic or other organ function, and d) if possible, be subjectively acceptable to the patient with minimal need for sedation. It has become apparent to those who manage these patients that volume controlled ventilators are the respirators of choice in the acute phase of the problem. Any medications that are used in the ICU to coordinate the patient with the ventilator should be potentially reversible. Since pain is prevalent in the post-operative period, the first line drug is intravenous narcotic (morphine). However, if the appropriate dose of narcotic cannot be used clinically (doses more than 1 mg/kg in a short period of time or hypotension develops), a long acting nondepolarizing muscle relaxant (pancuronium) is then utilized. Thus, the patient is effectively under anesthesia with a "balanced technique". When the patient still shows signs of sympathetic response (hypertension and tachycar-

dia), small doses of diazepam are added. Since diazepam is non-reversible, we prefer minimizing the use of it in this particular situation.

Initially, these patients may require a high inspired oxygen concentration to achieve an acceptable arterial oxygen tension ($P_{aO_2}=60$ mmHg). If oxygen is used inappropriately, pulmonary oxygen toxicity can develop.¹² There are 3 misconceptions about oxygen toxicity.¹³ First, there is no evidence that an inspired oxygen concentration of 40-50% or less produces pulmonary oxygen toxicity (other than in newborn). Second, there is no data available to show that significant toxicity develops in less than 24 hours (even if patients breath 100% oxygen). Third, there is no data available showing that patients with pre-existing pulmonary disease are more sensitive to development of oxygen toxicity. Indeed, the converse may be true that they may tolerate higher oxygen concentrations for a longer period of time. However, one cannot leave the patient on a high concentration of inspired oxygen because oxygen toxicity is an insidious killer. Thus, inspired oxygen concentration should be checked frequently. Oxygen should also be adequately heated and humidified to prevent drying of tracheobronchial secretion.

As we stated, the underlying cause of acute respiratory failure is loss of lung volume with decreased compliance. The use of positive end expiratory pressure (PEEP) can restore lung volume and thus improve compliance by preventing alveolar collapse and airway closure.¹⁴ The patient is given incremental steps of PEEP. That is, positive end expiratory pressure is added in 5 cm H₂O at a time. Blood gases are obtained 15-20 minutes after each respiratory change. The level of PEEP is determined by the patient's arterial oxygenation. If there is no improvement at 10, 15 or 20 cm H₂O, higher levels of PEEP can be used if the patient's cardiovascular system can tolerate it.¹⁶ When satisfactory arterial oxygenation is obtained, the inspired oxygen concentration is gradually reduced to 40-50%. One of the major purposes of PEEP is to reduce the risk of oxygen toxicity. PEEP is gradually reduced in 5 cm H₂O steps with continuous monitoring of the arterial gases. Relative contra-indications to PEEP included patients with: increased functional residual capacity (FRC), hypovolemia, infiltrative disease, respiratory fibrosis and asthma. However, if other measures fail to reduce intrapulmonary shunt, a therapeutic trial is indicated. One of PEEP's major physiologic effects can be a decrease in effective circulating blood volume and this can further cause hypotension and decrease in cardiac output. Therefore, means must be available to adequately monitor the intravascular volume, blood pressure and pulmonary artery pressure. It is also said that PEEP causes pul-

monary barotrauma (pneumothorax, pneumomediastinum and subcutaneous emphysema). Kumar has shown that in two groups of patients, one who received PEEP and one who did not, the incidence of pneumothorax and pneumomediastinum was identical.¹⁵ We feel that barotrauma is not related to PEEP but rather to the end inspiratory pressure. Thus, we try to keep the end inspiratory pressure below 50 cm of H₂O. If this higher pressure is required, the patient is monitored frequently for signs of pulmonary barotrauma. It is important to remember that the clinical condition of these critically ill patients may change rapidly and dramatically, so frequent and total assessment of the patient is mandatory.

The criteria used for weaning a patient from mechanical ventilation fall into two broad categories: physiologic stability and pulmonary function testing. First of all, we expect the patient to be stable. The level of consciousness must be adequate to support the airway and maintain effective ventilation. In terms of pulmonary function tests, the tidal volume, measured by a Wright® respirometer, should be 6 cc/kg; his vital capacity should be 12-18 cc/kg. Inspiratory pressure, an indirect measure of vital capacity, is then measured. Those patients who are not able to maintain -20cm H₂O of inspiratory force will probably not have adequate pulmonary reserve for effective cough following extubation. Since these are static tests, patients are then placed on "T-piece blowby" with humidified oxygen (40-50%). This tests the patient's ability to integrate the respiratory process over a period of time, usually an hour. Arterial blood gases are then obtained. If all are satisfactory, the patient is extubated. If unsatisfactory, the patient is maintained on blow-by or returned to assisted ventilation. Following extubation, pulmonary toilet is maintained with IPPB treatments with bronchodilator (if necessary), ultrasonic nebulization and postural drainage.

A new piece of apparatus has aided weaning patients from ventilators. This is called intermittent mandatory ventilation (IMV).¹⁷ The patient breathes humidified oxygen spontaneously and at preset intervals the lungs are actively inflated by the ventilator. Thus, if we give the patient "IMV 4", this means that the patient receives 4 mandatory ventilations a minute. The advocates of this system claim that the weaning is more physiologic since muscular coordination is maintained for a longer period of time. This is yet to be proven.

In summary, pulmonary complications in the post-operative period can lead to acute respiratory failure. Management should emphasize a) adequate pre-operative preparation, b) appropriate intra-operative monitoring and c) post-operative ventilatory support and pulmonary toilet.

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Intussusception in Children: A Review of 10 Years' Experience In a Community Hospital

Peter A. Immordino, M.D.

ABSTRACT—Twenty children with intussusception are reported over a ten year period from a medium size community hospital in southeastern Connecticut. Most patients were under 2 years of age. The oldest child was 9 years old. Three had definite causative lesions, 4 were reduced by barium enema. Of 16

operated upon, 2 had bowel necrosis requiring resection; both were 4 months of age and 1 had the only ileo-ileal intussusception. Transverse incisions were favored although no wound complications were noted. Seven had incidental appendectomy. There were no deaths no complications and no recurrences.

Intussusception in children is sufficiently common to be treated routinely in community hospitals, yet sufficiently uncommon to cause delay and difficulty in diagnosis and therapy. The purpose of this study is to review the diagnosis and treatment of this disease in a medium-sized community hospital.

The Lawrence and Memorial Hospitals is a 350 bed voluntary institution in southeastern Connecticut. Its location approximately one hour's distance from any major medical center and the large summer population of tourists have combined to attract a well-balanced staff of board qualified specialists from

many fields. Analysis of the treatment of intussusception in this hospital over the past 10 years is of particular interest to the community physician or surgeon who may be suddenly called upon to treat this emergency.

Materials and Methods

All cases with final diagnosis intussusception between birth and 15 years from January, 1964, through June, 1974, were collected by the record room librarian. Charts were individually inspected and the following information recorded for each patient: sex, age, symptoms, duration, initial diagnosis, presence of small bowel obstruction, associated conditions, physical examination, and barium enema result. On operated cases, the incision,

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presence or absence of bowel necrosis, causative lesions and duration of hospitalization postoperatively were noted. A few other items of individual interest were also reported, such as incidental appendectomy.

Results

A total of twenty cases are reported. Thirteen were between 4 and 9 months of age. The remainder were older. Fifteen were male. Initial symptoms included vomiting (12), pain (10), bloody stool (6), diarrhea (4), abdominal distention (3) and obstipation (1). Duration of illness ranged from 1½ hours to 1 week.

A mass was definitely felt in 8 patients, suspected in 4. Rectal blood was seen on the examining finger in 4 patients. Fever, pulse elevation, dehydration, distention and total absence or presence of high-pitched bowel sounds were noted in various cases. Evidence of small bowel obstruction was seen in six. Initial diagnosis was correct in 16. In the 4 with incorrect or doubtful initial diagnosis, prompt barium enema confirmed the true pathology.

Eighteen patients had barium enema for diagnosis or treatment. Only 4 patients were completely reduced by this method. Surgery on the remainder including 3 partially reduced by barium enema was carried out by eight staff surgeons. Three paramedian incisions were used. The remainder had transverse incisions with or without the use of "gridiron" technique. Except for one central incision, placement was on the right side but varied from the right upper to the right lower quadrant. No dehiscence occurred.

Two patients, one of whom had the only ileo-ileal intussusception, had bowel necrosis requiring resection. Both were 4 months old and were noted to be toxic pre-operatively, although two other children, ages 4 and 5 months, also showed signs of toxicity with fever, elevated white blood count and dehydration, but had no bowel necrosis. All the remaining cases requiring surgery had manual reduction.

Incidental appendectomy was carried out in 7 (6 ages 5-8 months, 1 age 8½ years). Of cases operated upon, one had Meckel's diverticulum, 1 cystic fibrosis and 1 an abnormal mesenteric band. Three had mesenteric adenitis. It was unclear whether this contributed to the intussusception.

There were no deaths and no recurrences either in those operated upon or in those reduced by barium enema.

Discussion

The great variation in incidence of intussusception in various parts of the world is well-known and unexplained. Hence the Hospital for Sick Children in Toronto reports 35 cases per year¹ and the Royal Hospital for Sick Children in Glasgow almost 30 cases per year², whereas the Boston Floating Hospital

and New Orleans Charity Hospital report only 6-7 cases yearly.^{3,4} Our age and sex distribution for this small number is shown in Figure 1.

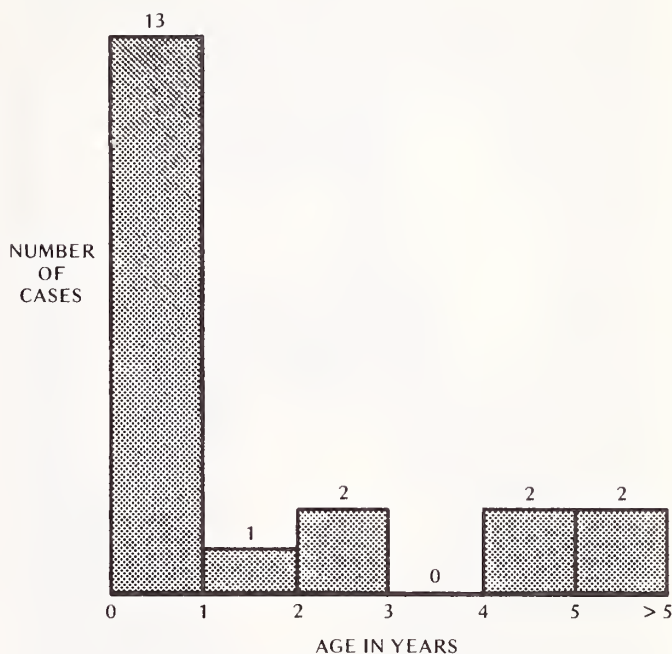


Figure 1
Age and sex distribution of cases.

Diagnosis was made by symptoms and physical findings in most cases before barium study. Vomiting and pain are the most common initial symptoms.^{1,2,4} In our series, 9 had either bloody stool or blood on rectal exam. About half the patients reported by Gierup et al⁵ had bloody stool.

Presence of a mass was noted in 8 cases, suspected in 4, a total of 12. This mass was felt in the right lower quadrant, right upper quadrant, midepigastrium, left upper quadrant or rectally.

Barium enema reduction occurred in 4 patients, although 18 of the 20 had barium enema preoperatively. The method of reduction has not been standardized at our hospital, some using manual manipulation, most keeping the enema bag no more than 3 feet above the table. One case thought to be reduced required surgery 2 days later because of recurrence. In retrospect the ileocecal valve was never completely reduced (Figure 2). No complications of barium enema occurred.

There are varying opinions on the use of this method. Ravitch⁶ feels every case of intussusception deserves a trial at barium enema reduction, whereas Benson⁷ in reporting a group of cases from Michigan stated that barium was not deliberately used therapeutically. Cases reported by Yoo and Touloukian⁸ and Naylor⁹ certainly dampen one's enthusiasm. Perforation occurred in the former with hand injected gastrografen, in the latter immediately upon installation of barium, the bag 3 feet above the table and no attempt at reduction having been made. Certainly



Figure 2

A Barium enema interpreted as showing reduction of ileocecal intussusception with "thumbprinting" around cecum, representing possible edema.

Ravitch's statement that gangrenous intussusceptum will not reduce if the cannister is kept below $3\frac{1}{2}$ feet must have exceptions. We hesitate to do barium enema in a toxic child and question its necessity in a neonate if the diagnosis is seriously entertained. Standardization of technique according to Ravitch's principles seems sound. Important rules to be followed are: 1. The cannister should never be more than $3\frac{1}{2}$ feet above the table. 2. If no progress is made in movement of the intussusceptum for a period of 10 minutes, the attempt should be abandoned and surgery carried out immediately. 3. The abdomen must never be manipulated. 4. After reduction of the ileocolic intussusception, the terminal ileum must be well filled with barium and good evacuation must result before one can be sure of complete reduction. 5. Ileo-ileal intussusception should not be reduced by barium enema.⁶

Causative lesions were found in 3 of the 16 cases operated upon. In addition 3 were noted to have mesenteric adenitis. A definite cause was found in 8% of operated cases from New Orleans Charity Hospital³, 9% from the Children's Hospital of Michigan.⁷ Swenson reported about 9% causative lesions from the Boston Floating Hospital excluding mesenteric lymphadenitis. In addition, he noted 26 of 61 ileocecal



B Flat plate taken two days later, showing mass in the midepigastrium, failure to fully evacuate barium and evidence of distended small bowel in the right lower quadrant.



C Barium enema showing recurrence of ilea-colic intussusception.

intussusceptions with variations of the fold of Treves, a congenital band from the cecum to the antemesenteric border of the terminal ileum⁴. This is a striking observation and unfortunately could not be ascertained in our series. We shall certainly observe this in the future.

Of 16 cases operated upon, 2 required resection. They were the two youngest of this series (4 months) and one had an ileo-ileal intussusception. Although both were toxic preoperatively, there were others equally toxic who did not have gangrenous bowel or irreducible lesions. Yoo and Touloukian in their series of neonatal intussusceptions reported 16 of 20 requiring resection⁸, thus pointing out the increased seriousness of this disease in the very young.

Placement of the incision seemed to depend on the location of the mass, although with partial reduction by barium enema, a transverse right lower quadrant gridiron incision should be the best. This allows inspection of the reduction of ileocolic intussusceptions and of most causative lesions. Manual reduction is carried out by pressure against the head of the intussusceptum, never by traction.⁶

Appendectomy was performed in 7 cases. Most patients in the hospital for Sick Children in Toronto had incidental appendectomy¹ whereas routine ap-

pendectomy in young infants is criticized by Dennison et al from Glasgow². We had no complication from this and certainly encourage it in older children. (We do not use the invagination method of incidental appendectomy).

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Paget's Disease of Bone: Recent Advances in Therapy

(This is the fourth of a series of five articles on calcium metabolism.)

Ernesto M. Canalis, M.D., Gregory R. Mundy, M.D., and Lawrence G. Raisz, M.D.

Paget's Disease of bone is a common disorder. From radiologic and post-mortem studies, lesions of Paget's Disease are found in about 3% of individuals over the age of 40. It is estimated that about 2.5 million people in the United States would have radiographic evidence of Paget's Disease on complete skeletal surveys. However, only a small proportion of these patients will have any symptoms due to bone disease.

Paget's Disease can affect any bone of the skeleton and may occur as an apparently single localized lesion or as multiple lesions. The distribution is characteristically patchy and irregular and the bones most commonly affected are the vertebrae, skull and pelvis (Figure 1 and 2). Bone pain is the most frequent presenting complaint. Patients may also notice local warmth and develop deformities, particularly, bowing of the legs and increasing size of the skull. Thickening of the petrous portion of the temporal bone in the

base of the skull may lead to deafness. Pathologic fractures can occur which involve the Pagetic lesion, most commonly in the femur, humerus, and tibia. The blood flow is markedly increased in Pagetic bone and overlying soft tissues, and arteriovenous shunting may be so great as to produce or worsen cardiac failure. Development of osteosarcoma in association with Paget's Disease is a much feared complication, but the high figures cited in the literature, ranging up to 10%, are probably the result of case selection. In large series, which include asymptomatic cases, the incidence of sarcoma is 1% or less.^{1,2}

Once symptoms of pain and signs of increased vascularity appear in Paget's Disease, one can assume that the lesion is active, but these changes may not persist. Prolonged symptomatic remissions can occur without therapy. Moreover, musculoskeletal symptoms are common in the age group in which Paget's Disease is most commonly found and symptoms may be due to associated inflammatory arthritis, or degenerative joint, or disc disease.

The cause of Paget's Disease is unknown. Morpho-

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Figure 1

Skull X-ray in Paget's Disease showing increased thickness of the vault, and mottled appearance with areas of osteosclerosis and areas of osteolysis.



Figure 2

Paget's Disease of pelvis showing irregular bony pattern with areas of osteosclerosis and areas of osteolysis.

logically it is characterized by markedly disordered architecture of bone, associated with increased activity of osteoclasts and osteoblasts. This is reflected in calcium turnover studies and measurements of hydroxyproline excretion which show markedly increased rates of bone formation and resorption. Some radiographic and biopsy studies suggest that the earliest lesions are osteolytic, and it is possible that the initial abnormality is an increase in osteoclastic activity to which bone cells respond locally with increased and inappropriate bone formation. The newly formed bone is disorganized in structure and the collagen matrix is often woven rather than lamellar. The osteoclasts are sometimes very large with numerous nu-

clei. Inclusion bodies suggesting the presence of viruses have been observed in osteoclast nuclei. On histologic examination of bone biopsies, adjacent areas may show either dominant bone resorption or new bone formation or even a normal cellular and trabecular pattern. Histologic studies may not confirm radiologic findings. Some patients who show radiologic osteoclerosis have predominant osteoclastic bone resorption on biopsy. Bone scans using agents such as technetium labeled diphosphonates show increased uptake at the site of active Pagetic lesions and are a good measure of both the activity and extent of disease (Figure 3).



Figure 3

Bone scan in Paget's Disease. Scan performed with technetium diphosphonate shows increased uptake in the pelvis, lumbar vertebrae, right scapula, and skull, all areas of active Pagetic lesions.

Laboratory studies rarely show any abnormality of serum calcium or phosphate concentration unless the patient is immobilized, when hypercalcemia may occur. The increases in bone formation and resorption are expressed biochemically by the increase in serum alkaline phosphatase and urinary hydroxyproline. The alkaline phosphatase, which is of the heat labile bone type, is a good measure of increased osteoblastic activity. The magnitude of the increase in alkaline phosphatase is a reflection of both the activity and extent of bone lesions in the disease. Total urinary hydroxyproline is an overall index of bone turnover. Hydroxyproline is an amino acid found almost exclusively in collagen. It is formed by hydroxylation of

proline after its incorporation into the collagen molecule. During synthesis of new collagen, some of the newly synthesized material is not deposited in bone, but partially degraded to non-dialyzable peptides. Hence, a high excretion of non-dialyzable hydroxyproline is an index of increased bone formation and is characteristically elevated in active Paget's Disease. During bone resorption, collagen is degraded more completely to low molecular weight peptides, often containing two or three amino acids, which are dialyzable. Hence, increased dialyzable hydroxyproline in the urine is a measure of the increased rate of bone resorption in Paget's Disease. While neither increased serum alkaline phosphatase or urine hydroxyproline are specifically diagnostic in Paget's Disease, both are useful biochemical parameters with which to monitor the activity of this disease and the effect of treatment.

Treatment of Paget's Disease

There are now three specific agents which can be used in the medical treatment of Paget's Disease of bone. Of these, only calcitonin has been approved by the Food and Drug Administration. The other two agents, mithramycin and edathamil, a diphosphonate, are being used experimentally, but it is not yet established that their benefits outweigh their risks. Both mithramycin and the diphosphonates can produce severe toxic side effects when given in high doses for long periods. Hence, their use for symptomatic treatment in Paget's Disease can only be justified if severe toxicity can be almost completely avoided by using low doses for limited periods. While all these agents have been shown to be effective, there are no concurrent controlled studies in which more than one of these agents was used and their efficacy compared. It is difficult to evaluate therapy because the symptoms in patients with Paget's Disease may wax and wane or may actually be due to osteoarthritis or other musculoskeletal disorders, which respond better to anti-inflammatory and analgesic agents.

Use of Calcitonin in Paget's Disease

The rapidity with which calcitonin has gone from a newly discovered hormone to a clinically useful agent is remarkable. During the 1960's, the secretion of calcitonin by the parafollicular cells of the thyroid gland was discovered, its effect to inhibit osteoclastic bone resorption demonstrated, and its structure and synthesis accomplished. Since 1970, its clinical use has been examined in a number of diseases and it has been found to be most useful in Paget's Disease. It has also been used in hypercalcemia and osteoporosis, but as presently employed, its effects are not sufficiently reliable or long lasting and calcitonin has not been approved by the FDA for use in these disorders. In

Paget's Disease, calcitonin treatment produces a rapid decrease in osteoclastic and osteoblastic activity, so that bone turnover decreases. Ultimately, the Pagetic lesions may be replaced by normal bone, but complete histologic healing has not been demonstrated. Between 60 and 90% of patients have been reported to show good clinical responses to calcitonin therapy.^{3, 4, 5, 6}

The major indication for therapy in Paget's Disease is bone pain. Treatment may also be indicated in patients with progressive deformity, deafness or other signs of nerve compression, or in some patients in whom cardiac failure might be improved if the excessive arteriovenous shunting and high cardiac output seen in Paget's Disease were diminished. However, the usefulness of calcitonin in treating nerve deafness and cardiac failure has not been established. Major drawbacks to calcitonin therapy are that it must be given parenterally and that it is expensive. A month's supply will cost from \$25 to \$75 depending upon the dose. In addition, the incidence of treatment failures and relapses is fairly high.

The clinical benefits of calcitonin are usually greatest during the first six to twelve months of therapy. Relapses occur with increasing frequency during the second and third year of treatment. Bone pain usually improves gradually over several months. The serum alkaline phosphatase may begin to fall after only two weeks of therapy and then continue to decrease. However, alkaline phosphatase usually does not decrease to normal. The decrease in urinary hydroxyproline excretion shows a similar pattern. Patients require at least 8 weeks of therapy before they can be considered a treatment failure.

In addition to symptomatic improvement and changes in urinary hydroxyproline and serum alkaline phosphatase, changes in radiologic appearance and bone scan may be used to monitor response. The correlation between these various parameters has not yet been established. Because Paget's Disease is characterized by remissions and exacerbations of symptoms as well as signs, it is important to use multiple criteria to monitor treatment.

Currently at the University of Connecticut we are attempting to assess the usefulness of bone scans for monitoring therapeutic response to calcitonin. The uptake of technetium labeled diphosphonate is markedly increased in active Pagetic lesions and this uptake may decrease with successful therapy. It is possible that bone scans will provide an earlier and more sensitive index of the efficacy of therapy before the effect on symptoms and biochemical parameters is apparent.

Thus far, calcitonin has appeared to be quite safe for long term use. Its side effects include nausea and

anorexia, facial flushing, swelling of the hands, and occasional skin rashes. These are usually transient and do not require cessation of therapy. A wide variety of therapeutic schedules have been employed. The most common method is to administer 100 MRC units three times weekly. In one series using this regimen, 70% of patients showed a good response which lasted from six months to two years. Relapses occurred with increasing frequency on prolonged therapy, associated with return of symptoms and elevation of serum alkaline phosphatase and urinary hydroxyproline. The explanation for this escape from the beneficial effects of calcitonin is not known. It may be due to development of neutralizing antibodies, to secondary hyperparathyroidism, or to the same escape phenomenon which occurs when calcitonin is used in hypercalcemia, that is, the development of resistance of bone cells to the effects of the hormone. If neutralizing antibodies are the cause of escape, then responsiveness might be restored by substituting human calcitonin. However, human calcitonin is not yet available for use in this country. It is not known whether patients who relapse on salmon calcitonin, but do not have antibodies, will respond to human calcitonin.

In summary, while calcitonin does not cure Paget's Disease of bone, it is safe, and has a beneficial effect in many patients. It is indicated mainly to relieve symptoms, and salmon calcitonin given according to the schedule described above will diminish bone pain in most patients. While it is conceivable that calcitonin might be useful in asymptomatic patients to prevent complications or progression of the disease, this has not yet been demonstrated and we do not recommend its use for this purpose.

Other Forms of Treatment in Paget's Disease

As noted above, calcitonin is the only specific therapy for Paget's Disease which has been approved by the FDA. Mithramycin and diphosphonates are being studied and may prove to be useful as well.^{7, 8, 9}

The diphosphonates are stable synthetic analogs of pyrophosphate. They inhibit bone resorption and mineralization presumably because they bind to hydroxyapatite and block further crystal deposition and dissolution. The agent currently available, edathamil, or ethane hydroxydiphosphonate, has the additional property of inhibiting the formation of the active vitamin D metabolite, $1,25(\text{OH})_2\text{D}$, at high concentrations. Thus, this agent can produce osteomalacia which can itself cause bone pain and pathologic fractures. Some patients treated with edathamil at the originally recommended dose of 20 mg per kg per day, showed an excellent initial symptomatic response, but then developed symptomatic osteomalacia, some-

times after the therapy had been discontinued. Lower doses may produce a less rapid response, but may be less likely to produce osteomalacia. In addition, other diphosphonates are currently being studied which might not have such adverse effects on mineralization and vitamin D metabolism. If these problems can be resolved, diphosphonates would be convenient because they can be given orally and because they have long lasting effects which do not appear to be easily reversible.

Mithramycin is an anti-tumor antibiotic which inhibits DNA dependent RNA synthesis. It has been used successfully in many patients with hypercalcemia and in a few patients with Paget's Disease.¹⁰ Its major effect appears to be to inhibit bone resorption, but this may be achieved by killing bone cells. Mithramycin is also a general toxin and its toxic effects may be cumulative. The major side effects are nausea, vomiting and diarrhea, bone marrow depression, thrombocytopenia and liver damage as reflected by release of hepatic enzymes. It may also have a direct toxic effect on the renal tubules. Since mithramycin is excreted by the kidneys, its toxicity is enhanced when glomerular filtration is decreased. This is a problem in patients with Paget's Disease who are often elderly and have impaired renal function. Mithramycin is given by intravenous infusion in small doses in Paget's Disease. Because of the potential serious and cumulative toxic effects, it cannot be recommended for general use in Paget's Disease at present; however, further studies of low doses in selected patients are warranted.

In addition to specific agents, analgesic and anti-inflammatory drugs are sometimes beneficial in patients with Paget's Disease. Aspirin, indomethacin, and glucocorticoids have been used with symptomatic response. Some of these patients may have had symptoms due to musculoskeletal disorders other than Paget's Disease. However, these agents can inhibit bone resorption under certain circumstances. Aspirin and indomethacin would be expected to have an effect if increased prostaglandin synthesis were a pathogenic mechanism. Finally, local radiotherapy has been used successfully in some patients.

Conclusion

Paget's Disease of bone is a common disorder, but one with quite variable clinical expression. Symptomatic Paget's Disease can be treated effectively by calcitonin, but the number of treatment failures and relapses is high. The newer agents currently being studied, diphosphonates and mithramycin, are effective but potentially toxic. Hence, additional agents should be sought for the treatment of this disorder.

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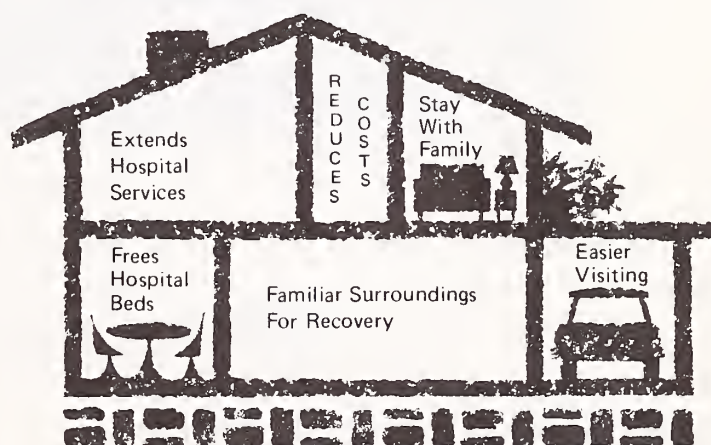
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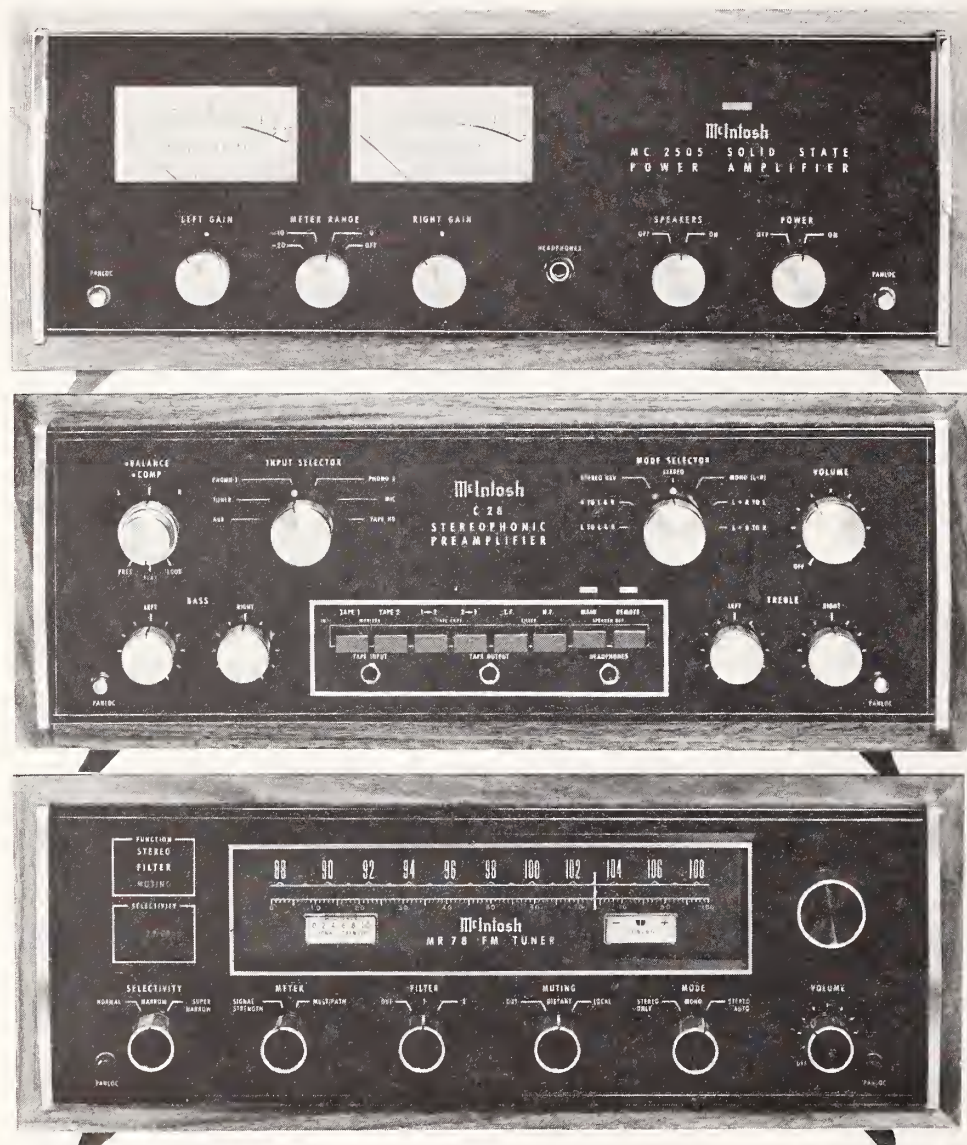
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Ethical Considerations in Fetal Research

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Introduction

We regard the human fetus as part of the human community and as such believe that the fetus should legitimately benefit from the main goals of the medical profession, i.e. the optimizing of human potential for a full and healthy life, the prevention of disease and deformity, the return of the diseased human being to a healthy state, and the minimizing of suffering. The recognition of the legitimacy of the fetus as a patient requires of the medical profession attempts to learn how to fulfill these goals. This requires that the human fetus participate in research whose aim is the accomplishment of those purposes.

As with any other class of research subjects, it is paramount that safeguards be secured which insure that adequate experimental work has been performed in other systems where applicable, that risks to the research subjects be acceptably low, that the information sought by the research be deemed significant by the biomedical community, and that legal and ethical norms of our society be central to the design and execution of experimentation.

It is evident that large numbers of fetuses do not enjoy an optimum intrauterine life and start extrauterine life with diminished potential. Many fetuses succumb during intrauterine life or are born diseased and require extensive therapy which, by that late date, may be ameliorative only. Estimates suggest that 25% of fetuses die in utero and another 2% die at the time of birth or in the first week of life. About 3% of all live born infants have a serious disorder

diagnosable at the time of birth apart from problems of prematurity.

Fetal disease and disorders provide a massive medical problem and one which must be addressed by an ethical profession. Abandonment of the fetal patient is clearly unethical and abhorrent to the profession. Prevention or correction of disease during fetal or neonatal life, prevention of death at that period in life, and providing an environment conducive to optimum development are benefits for that human individual which extend over the entire lifetime, a potential of seventy or more years.

The child and infant for many decades did not benefit proportionately with adults from advances made in medical science. Energies and monies expended for the control of medical problems during childhood have historically been much lower than those expended for the problems of the adult population. The fetus is even more vulnerable in this regard. The child, the infant, and the fetus are not capable of sounding their own advocacy and must depend upon other members of the human community. The concept that the fetus is a therapeutic orphan has substantial validity when one considers the proportion of the biomedical research effort extended for the fetus and contrasts that with efforts made at controlling diseases of the adult population.

It seems that the diseases of adulthood and aging continue to receive wide popular support from a political constituency that views these diseases as more immediate threats than it views diseases of the fetus. This situation continues even though evidence is accumulating that fetal research, including the understanding of growth processes and of fetal diseases, may play a key role in solving problems of adult-onset diseases. But even considering the fetus alone, we believe that progress in curtailing and preventing diseases of fetal onset should have priority and will result in great benefit both to the individuals

This article is taken from a report to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled "The Nature and Extent of Research Involving Living Human Fetuses." The report was prepared by Dr. Mahoney in collaboration with the six other authors listed here and was presented to the National Commission in 1975 to aid the Commission's investigation of fetal research. That investigation culminated in recommendations which formed the basis of current federal regulations for research involving pregnant women and unborn human infants.

and to the collective society. We further believe that fetuses and neonates, as classes of human beings, have the same right to benefit from medical progress as do other groups in our community.

The Viable Infant

Any viable live born infant should receive the best possible medical care including experimental therapies performed under appropriate safeguards. This is a first responsibility of the medical profession and of the community. To stay on the safe side of this duty, any possibly viable live born subject should be included in this class. At the present time this might include all subjects over twenty weeks' gestational age or over 500 grams. Viability is primarily a statement about technology, not about the fetus. Thus a statement about viability is a relative statement and must be reassessed periodically. We believe that this reassessment should be made at annual or biannual intervals.

In this view, viability cannot be equated with personhood, but can only be the basis for practical line drawing at a particular moment and place. The most important reason for drawing such a line as it applies to human experimentation is the desire to avoid an injury to a fetus that will survive. To avoid this possibility, a definition of viability should be drawn below the lower limit of possible viability at a given time. We believe that the viable infant, even though born very early in gestation, is conceptually no different than the full term newborn infant and that considerations of research with these human subjects requires the same regulations as applied for the protection of infants and children.

The Deceased Fetus

We consider that the fetus which is clearly dead after delivery should be viewed as any other dead human being. Legal regulations and ethical constraints on the handling of the deceased human being should be applicable to the dead fetus. These should permit removal of still living tissues or organs for biomedical research and therapy functions. Examples would include the carrying out of planned experimentation to learn about fetal metabolism, physiology, or disease; beneficial therapy for other human beings like transplantation of fetal organs, and the teaching of health professionals who must be the guarantors of continued care and progress in fetal medicine for the future.

For some studies, such as examination of brain ultrastructure and metabolism, the transplantation of some tissues, or possibly the recovery of very fastidious viruses, access to tissues would be required very soon after death. This means that the definition of death becomes important and we suggest that this

definition focus on the whole organism. We further believe that the use of the dead human fetus for any of the above cited purposes must be contingent upon consent of the person who retains legal responsibility for the deceased fetus. In almost all circumstances this would be the mother or both parents. We do not believe that the deceased fetus should be viewed differently if from a spontaneous abortion rather than an induced abortion and we know of no evidence to suggest that use of tissues from deceased fetuses increases requests for abortion.

Informed Consent and the Mother

Problems of informed consent are central to the current societal debate about all kinds of human experimentation and we do not propose to comment extensively on problems dealing with the consenting adult. When a mother is a co-participant in fetal research, such as when an abortion is contemplated, her clinical needs must continue to have primary consideration. Thus the timing and method of abortion should not be altered in a way that would place the mother at significantly increased risk for the purpose of experimental design. We do believe however, that the pregnant woman, who has received adequate information, should retain the option and be free to participate in approved research; at times this could include an alternate method of clinical care.

Considerable controversy exists about the relationship of an investigator who does fetal research and a mother who may elect or has elected abortion. It is obvious that investigators cannot be influencing women to decide whether to have an abortion. After a decision to abort a pregnancy has been made, the investigator should have a close relationship to the mother if the investigation will start either before or during the abortion procedure. The mother needs to know the investigator and she must feel that the investigator will be continually cognizant of and responsive to the mother's interests. The participation of another person as intermediary may at times be desirable but at other times unnecessary.

Informed Consent and the Fetus

We believe that the human fetus is a legitimate participant in the human community. The human being is a social species. A social contract is entered into by the members of the species for their own protection and for the benefits of collective action to enable a more satisfactory life for all members of the community. This social contract has definite limits in our society and does not include the acceptance of undue risk or any mandate to self sacrifice. It does include a mandate for cooperative behavior for the benefit of other members of the community and this

includes, most importantly, the preservation of basic human individual rights.

It seems evident in observing adult members of our community that actions are often taken for the purpose of benefitting other members of the community. Thus we see consenting adults freely participating in medical research which has no immediate benefit to that person. This is done by healthy individuals and also by individuals who recognize that their death is imminent. The important consideration in participation by these individuals is that they have the ability to consent to their own participation. Consent by the fetus is an impossibility. Nonetheless we believe that it is reasonable to view the fetal members of the human community in this regard similarly as adult members.

We believe that asking fetal participation for the purpose of advancing medical benefits for the class of human fetuses under stated circumstances is acceptable and ethical. These circumstances are that the information being sought is important to biomedical advance, that the information cannot be obtained except by the participation of human fetuses, and that the risks involved are acceptably low. We believe that a scientific and ethical review process and an advocate for the individual human fetus should both agree that any proposed research is acceptable. To eliminate the participation of human fetuses from experimentation because they are unable to consent, denies fetuses as a class the right to benefit from medical progress and directly contradicts the presumption that the human fetus is a legitimate participant in the human community.

In our human community all individuals participate in human experimentation without their consent at all times. There are planned and unplanned manipulations of the environment including the addition of large numbers of pollutants, and the application of many types of social and psychologic pressures. Usually, analysis of the effects of such manipulations is retrospective. Nonetheless, we recognize how important planned observation and control of many of these parameters are to prevent harm to those living today. This is just as true for the fetus and for the many fetuses yet to be conceived.

Planned experimentation and controlled prospective observation give a much increased likelihood of preventing harm than the often unplanned way of acting. Again, fetuses as a class should legitimately benefit from this type of planned experimentation via the mechanism of proxy consent by an informed advocate.

Relationship to Societal Ethics

Research must be guided by the ethical norms of our society. Over centuries there has been advance in

the human's view of his or her fellows; actions which would be regressive in this regard should not proceed. Thus activity which would be viewed as dehumanizing or debasing to our concept of the human individual should be proscribed. We further recognize that in a pluralistic democracy that there must legitimately exist different views of the human individual and the nature of humanness or personhood.

We feel that no person should participate or have pressures placed upon him or her to participate in research which violates that person's ethical concepts. We further believe that the view of one segment of our population should not dictate the activities of other large segments of the population as long as fundamental human rights are preserved.

We suggest that any given experimentation should receive rigorous review for both scientific and ethical content and that this review be carried out by review boards which are informed about the scientific and ethical issues and which are representative of the community.

We believe that primary review should occur locally and that there be options for coordination and analysis of the local review process at a national level. Scientific and ethical assessments are equally important. Scientific assessment must consider experimental design, the nature of the information desired, risk-benefit analysis, and the use of appropriate alternate means to gain information where applicable. A review board must be assured that this kind of scientific assessment by appropriate competent persons has been carried out. Ethical analysis must be just as rigorous and must heed the community in which experimentation is being done.

We see a twofold reason for not allowing experimentation which is deemed dehumanizing by a large segment of the community. First, activities of this type may, by a process of slow spread of ideas, undermine the view of the human individual within the scientific and medical communities. We know of no evidence to suggest that such a phenomenon occurs but we agree that a reversal of improved or increased concern for other human beings must be guarded against. Another phenomenon is more easily documented when experiments are carried out that are unacceptable to a community. There results a reaction against the scientific and medical fields such that support of experimentation to enable medical progress is withdrawn. Thus, in this pragmatic sense, experimentation which is offensive on ethical grounds has the effect of decreasing all human experimentation, thereby violating a central ethic of the medical profession to continually seek better methods of prevention and therapy.

The Fetus in Utero

The fetus in utero or in process of being aborted provides a more difficult ethical analysis than does the dead fetus or the living viable infant. There is a presumption of viability at any stage in gestation for the living fetus as long as it remains inside the uterus. Thus experimentation involving that fetus must have acceptably low risk of any harmful effect on viability or on the potential for meaningful, healthy life.

If the process of abortion has begun, the life of the fetus will soon end. There is debate about whether different standards apply in that situation and we disagree in our own analysis. One view holds that no risks can be imposed that would not be acceptable for the fetus which was continuing life. Another view will accept an increase in risks if the information is important and alternate ways of obtaining the information are not practical, if the methods of the experiment are acceptable in themselves (i.e. would be used in other classes of human subjects), and if the process of dying for the fetus were not altered in an unacceptable way. In any event, expected benefits from the experimentation still must be clear and must require the use of the human fetus to gain the desired information.

Ethical considerations as to sensory perception by the fetus also must be addressed. We know of no evidence to suggest or support a contention that the fetus at mid-gestation or earlier, when abortions are performed, is aware of pain or has a psychologic fear of death. We would prefer seeking such information rather than assuming or ascribing these anthropomorphic parameters of later life to this early stage of human development when the central nervous system is relatively primitive.

We do not believe that the fetus which will die by elective abortion or is in the process of dying should be automatically excluded from experimentation. Imminent death does not automatically exclude participation of children or adults from medical research. Assessment of an individual research protocol must still look at the nature of the information sought, the necessity of using this group of human subjects, and an analysis of whether there was any increase in suffering entailed by the dying subject. Experimentation in anticipation of abortion or in process of abortion should not be categorically prohibited but again should be assessed in terms of risk to the fetus as well as risk to the mother.

With regard to experimentation which starts before abortion starts, we note that there are many procedures of minimal risk that can be applied to the intact pregnancy which could yield important information by examination of an aborted fetus at a somewhat later time. These procedures are noninvasive or minimally invasive such as the use of

sound waves to obtain fetal measurements for correlation with the abortion or administration of a drug or chemical in trace amounts, perhaps tagged with a nonradioactive isotope like carbon 13. It would be important that risk to the fetus were very small, so that if the fetus should survive to viability, there would be little likelihood that it would have been harmed. Careful assessment of the individual research protocol should be the paramount activity rather than categorical prohibition.

The Living Previable Infant

Experimentation with the living previable subject outside of the uterus falls into two classes. In the first there are efforts to replace the many functions of the maternal placenta with artificial alternatives. If this research is meant to be beneficial to a class of fetuses which cannot survive outside of the uterus at the present time, appropriate work must have been done in other species, and careful risk analysis should precede application of the new technologies to the human fetus. The other class of research with the previable fetus is research which is not beneficial to that particular subject although it would be expected to be beneficial to other fetuses. In this instance it appears paramount to avoid the possibility of the fetus surviving with an injury derived from a nonbeneficial experiment.

If one views the immature infant as being nonviable as a consequence of the inadequacy of technology rather than a statement about the lack of personhood in the fetus, then the previable infant can be seen as comparable to an adult with a disease or physiologic derangement which renders that person unable to continue life because a technological solution to the problem does not exist. The impending death of the adult would not deprive that person of certain protections as a possible experimental subject nor would it exclude the individual as a possible subject. The patient would presumably consent, or an advocate would consent, only to those procedures which sought important information, unobtainable in any other way, with minimal risk. These same guidelines should be applied to the previable infant outside of the uterus.

Parental Rights

In considering the ethics of fetal research, the rights and expectations of currently living adults must also be recognized. Today there is major concern about restricting the human population of the world and of conserving natural resources. With attempts to restrict the quantity of human beings born there is a natural wish to maximize the potential that each human being has at the time of birth. Thus, the quality of each child is a major and legitimate concern of each individual parent. Parents have historically

been given the right of advocacy for their children and this continues to be the most likely group to best protect the interests of the child, born or unborn.

We believe that parents should be allowed to participate in medical research for the benefit of their own offspring and of future offspring and to have their children, both born and unborn, participate when the risks are acceptably small and the information sought deemed important. Fetal research has been of great benefit to many families desiring to have normal children and can be of continued great benefit in providing normal children to future families. The government through its tax structure and its involvement in the economy already exercises considerable pressure upon the reproductive decisions of individuals in this country. It should even more be the government's role to continue to support research which will give options for reproductive decisions that have a better and better likelihood of resulting in normal children.

Induced Abortion and Consent

The consent process by which fetuses participate in research has aroused most controversy when considering research involving a subject before, during, or after elective abortion. In other circumstances it would seem that the mother or parents are the most likely to protect the interests of their fetus. In the setting of elective abortion, the mother has rejected the possibility of life for her fetus and many persons have questioned whether she any longer can represent the interests of the fetus. It is possible, however, that the mother may continue to be the best advocate even in the setting of elective abortion. It is our experience that the mother continues to consider the welfare of her fetus during abortion and afterward. At least it would seem that should she have objection to participation of her fetus in an experimental protocol, that the fetus would not participate.

Another source of advocacy for the fetus does exist. This is the review process that assesses the

acceptability of the research. When the research is deemed acceptable for a class of fetuses, then the problem of consent for an individual fetus must be faced. A variety of procedures for selecting an advocate in addition to the mother could be proposed.

Regulation of Fetal Research

There is concern about the difficulty of substantive policy achieving an acceptable degree of ethical "rightness" when it results from a process which is so layered over with political, personal, religious and other conflicting pressures.

The previous method of protecting the rights of human subjects in this society has been through procedural safeguards rather than policy on discrete issues of substance. While such procedural safeguards have had a short history, and were preceded in this country by a long era of episodes which would now be considered unethical experimentation, our review of fetal research suggests that the system has worked well and that the number of ethically questionable studies is a miniscule part of the whole. Even in those few instances, the projects have been discontinued in this country.

If this analysis is accurate, there would be considerable advantage to a policy which required a vigorous review process, coupled with mechanism and resources for exposure and broad discussion of controversial issues. Such a policy would be more flexible and adaptable to the rapid changes in this field, and would reduce the dangers of a policy resulting from political pressures rather than reasoned ethical consideration of all relevant data.

For these reasons, it is the recommendation of this study group that the final policy recommended by the Commission be one which includes an ample exposition of the many legal, ethical, and medical issues but which mandates only a vigorous review process rather than specific restrictions.

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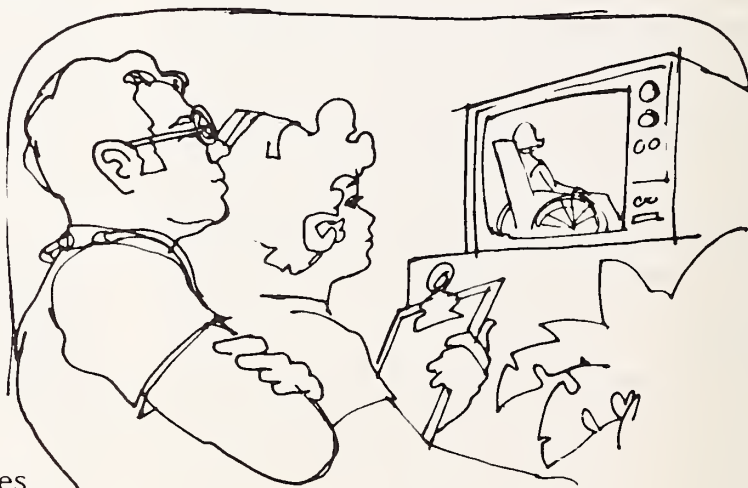
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Marihuana: Current and Recurrent Issues in Connecticut

Donald Pet, M.D.

Introduction

This article is a brief review of salient current information on marihuana extracted from the 8 month study and report of the Connecticut Drug Council's Ad Hoc Committee to Study Marihuana.¹ The charge to the seven appointed committee members² was to review and assess Connecticut's approach to marihuana use—to review current scientific findings on marihuana, its use and abuse, and to make specific recommendations appropriate for Connecticut. In addition to reviewing considerable literature and travel to important sources of information, 5 national authorities³ gave testimony to our committee.

Chemistry and Pharmacology

Marihuana is a preparation of the dried flowering tops and leaves with variable proportions of seeds and stems of the *Cannabis* plant. Its potency varies greatly; sometimes there may be no psychologically active ingredient at all. Because the primary active ingredient 1-delta-9-trans-tetrahydro-cannabinol (delta-9-THC) was only identified and isolated within the last 10 years, it has been difficult to compare studies. More than 40 constituents of marihuana have been isolated and not all have been identified and tested. Dr. Carlton Turner, based on his experience of growing and assaying marihuana for the Federal government, told us that cannabidiol has recently been found to diminish the activity of THC. Thus, marihuana high in THC but also high in cannabidiol may be less potent than marihuana of moderate THC but low cannabidiol. Such a phenomenon would

suggest that all of the dose controlled studies which have not evaluated cannabidiol content (virtually all studies to date) may require softer interpretation.

Delta-9-THC content may vary from 0 to 7% whereas the generally more potent sticky resins (hashish) collected from the plants flowering tops may reach 10% THC; however, poor quality hashish may have less active ingredient than good quality marihuana. Of further interest is that the delta-9-THC acid present in marihuana is decarboxylated to the more active form of THC by heat. Thus, marihuana is about three times more potent by smoking than when ingested. A current source of concern is the introduction of distillation methods to achieve concentrations of active ingredient approaching 90% THC ("hash oil").

After smoking marihuana, peak levels are reached in approximately 10 minutes and fall after several hours. There is presently no satisfactory low cost practical screening assay for "intoxication" with marihuana. The adequacy of identification is frequently challenged in court cases resulting often in acquittals. Moderately expensive accurate analytical techniques utilizing gas chromatography and mass spectrophotometry are available. Improving technology may soon produce low cost screening methods. Because THC binds strongly to lipoproteins, unlike alcohol, prolonged use may lead to storage in cell membranes, especially nerve tissue; the clinical implications of this property are not well delineated.

Marihuana's Effects

Signs and symptoms: the most consistent objective changes in man are increase in heart rate and conjunctival reddening—the latter occurs even with oral use. Beyond that, there is little for the observer to consistently observe. The experienced user is often capable of concealing use. Common reactions include laughing and giggling, relaxation, decreased sense of fatigue, garrulousness, an increased sense of awareness of music, odors, sex, food and so on, slowing of time, fantasies, difficulty in concentration and especially short term memory, increased appetite, dryness of the mouth and throat. For some, effects may be just the opposite as above and clearly vary with the set and setting, dose, user, etc. Violent and aggressive behavior is not usual and serious toxic effects have not been observed in humans. There were no known reported deaths from overdose; marihuana may be one of the least lethal of all drugs. Atypical reactions are often explained by the common practice of adulterating marihuana

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All members of the Ad Hoc Committee to Study Marihuana contributed to the original report. The author assumes responsibilities if the selections for this review are not felt most representative by his colleagues.

1. "Marihuana: A Guide to Developing An Informal Social and Legal Policy"—Full report available from the Connecticut Drug Council, 90 Washington Street, Hartford, Connecticut, 06115.
2. Donald Pet, M.D., Committee chairman (UConn Health Center), Mr. Terry Capshaw (Director, Adult Probation), Jerry Frankenheim, Ph.D. (UConn School of Pharmacy), Herbert D. Kleber, M.D. (Yale University School of Medicine), Karl A. Neiforth, Ph.D. (UConn School of Pharmacy), James E. O'Brien, M.D., Ph. D. (UConn Health Center), and the late John F. Bianchi (State's Attorney). In addition, Roland Metivier, M.A. (presently Conn. Alcohol Council) collaborated, and Joseph Sullivan (Conn. Drug Council) served as staff coordinator.
3. Gabriel Nahas, M.D., Henry Brill, M.D., Carlton Turner, Ph.D., Erich Goode, Ph.D., and Thomas Ungerleider, M.D.

with other substances ("supergrass", "angel dust", etc.).

Medical Use: Although tincture of cannabis was commonly medically prescribed prior to the 1937 Marihuana Tax Act, there is currently no approved usage by the F.D.A. Prior application was for a broad variety of conditions including pain, migraine, excessive menstrual bleeding and cramps, cough, for terminal illness, as a diuretic, an antibiotic, for ulcers, epilepsy, insomnia, anxiety, as a general tonic, drug withdrawal, and others. New therapeutic possibilities such as anti-tumor, anti-glaucoma, and immunosuppressant properties are being considered.

Medical Concerns: Suspicion has been raised in several areas. These findings within basic science are for the most part still controversial.

- (1) Lung irritation—precancerous lesions, emphysema, decrease in vital capacity, possible chronic irritative and inflammatory processes, as with cigarettes.
- (2) Impairment of the immune response which enables the body to resist foreign substances as viruses and bacteria.
- (3) Alteration in DNA formation, the key substance in chromosome formation and inheritance patterns for future generations.
- (4) Reduction of the male hormone testosterone with long-term use (possibly related to breast enlargement in the male).
- (5) Other diverse effects such as weight gain, growth hormone changes, tumor resistance, and so on.

Definitive adverse clinical manifestations have been difficult to demonstrate with unanimity among the experts. Despite considerable basic and clinical studies, no clear cut non-controversial, specific dangers have been demonstrated with use of marihuana in moderation. Marihuana ranks low in harmful or negative health changes relative to other drugs such as alcohol, opiate narcotics, stimulants, and sedative hypnotics. It is presently ranked lowest among drugs which are abused with respect to severity of adverse consequences to the individual and to society (White Paper on Drug Abuse, September, 1975, p. 33). Yet marihuana is *not* a harmless drug. It is an intoxicant, can cause hallucinations, temporarily interfere with short-term memory, alter mood, and has specific pharmacologic actions that are not completely understood.

Related Health Considerations: The existence of the "amotivational syndrome" involving lessening of social drive, judgement, concentration, memory and apathy is questioned by some who demonstrate fair numbers of regular users who are top students

or productive and highly committed to their respective interests. Marihuana intoxication may cause altered spacial perception, alertness, coordination, judgement, dexterity, and mental imagery. These effects have implications for any task where safety may be compromised by the above. Some persons advance the hypothesis that use of marihuana will lead to the use of other chemicals, especially illicit ones. A contrasting argument is that the status of the law itself, more so than any property of the drug, increases the graduation effect through a process of *association*. Smoking the first "joint" immediately puts one in a criminal element unlike the situation with cigarettes. Whether marihuana use provides a "stepping stone" to other drugs or whether the illegal status of marihuana predisposes the casual user by *association* to the other drugs are still matters of controversy.

The medical effects of marihuana are often compared to those of alcohol where there is a very high mortality and morbidity rate—viz. medical complications to virtually all body organs with chronic use, especially the liver, intestinal tract, and central nervous system. Critics of harsh marihuana laws often cite such statistical data to suggest we have an irrational policy of drug usage and support a contemptuous attitude towards criminal penalties associated with marihuana. Alcohol seems to diminish inhibitions and unmask aggressiveness whereas chronic marihuana users are more likely to be described as talkative, lazy and less prone to crimes of violence.

Further Considerations for Developing a Rational Social Policy

There are a number of recurrent themes that appear in the marihuana debate as to how we should best deal with the substance marihuana. Should the decision be that of the physician, the religious leaders, the politicians, or arrived at through a town hall debate? There are a number of determinants felt to be important by the committee which are "opinionistic"; yet, in these issues seem to lie more important considerations than the scientific findings previously reviewed.

1. **Criminal vs. Civil Sanction**—The U.S. is bound by the 1961 Single Convention not to legalize; the State's choice is the imposition of *criminal sanctions* involving possible incarceration or *civil sanction*, involving, for deterrence, the imposition of a fine, as with a parking ticket or the requirement to attend an educational program. The debate centers on the choice of decriminalization (civil sanctions) rather than legalization as is the case with alcohol.
2. **Legal Objectives**—Our committee was in general agreement that marihuana is not harmless, the

dangers to the user of the community appear less than with alcohol, that criminal penalties for possession of small quantities for personal use appeared too severe (but how much?), and that any message to diminish criminal penalties must be conveyed in such a manner so as not to be interpreted as a sanction to use marihuana.

3. The Effect of Lessening Criminal Penalties—

There appears no clear evidence that lessening penalties for simple possession would increase demand. Oregon, the first of six states to decriminalize in 1973, has experienced no substantial increase in use. Less substantiated but frequently argued is the view that trafficking will increase as well as demand, that it is far harder to tighten a “permissive” law (viz. alcohol) than to “wait and see,” and any increase in users will increase the absolute number of abusers.

4. Pros and Cons of Criminal Penalties—

Prosecutors may favor criminal penalties for possession so that an individual with a more severe but perhaps unprovable charge may bargain down to the lesser, but provable charge, so called “Plea-bargaining.” In addition, the threat of criminal penalties encourages the consumer to “cooperate” with enforcement to identify the dealer. Another view is “why bother—we have *de facto* decriminalized possession without changing the law.” Rarely is one incarcerated for simple possession. This position requires faith that the criminal justice system will, indeed, use discretion and fairly and consistently interpret the law. The opposing argument states that those in simple possession for personal use suffer the embarrassment of “arrest,” have a criminal record which may later prevent a job or educational opportunity, must pay legal fees, are placed in conflict with parental attitudes, and fill court time needed for problems more injurious to the community. Further, such a law tends to be unevenly applied depending on the policy of the towns’ police chief; some subjects may not pass the “attitude test” or be at a disadvantage if they possess long hair, or are among a minority group or low social economic group. One expert witness, for example, indicated that the same affluent persons advocating criminal sanctions want *their* children to escape criminal prosecution and have treatment or forgiveness when in trouble.

5. Our Ability or Will to Enforce the Law— Does it really make any difference at all what the law is if we don’t enforce it or do so in a token or inconsistent way? Laws that are advertised but not enforced, it is argued, simply create a mockery and lack of respect for the enforcement agency

specifically, and society in general. Of 26 million persons in the U.S. who have used marihuana, 500,000 persons were arrested in 1974. About ⅔ of possession cases involved one ounce or less. Incarceration is rare. While we clearly have inconsistencies, it appears difficult to develop a law that is rational and can be *consistently* enforced.

6. Considerations for Legalization— With an illicit market, there is no way to impose age, strength or quality controls. With proper controls, the potential harm from marihuana might be minimized. Proponents of licit distribution of marihuana also advise of the benefits through generating considerable tax income. However, as mentioned, legalization is not currently a political option due to international treaty obligations. Legalization of marihuana is opposed by approximately 80% of the public.

7. The Ethical Consideration— Our society has been primarily governed by a Puritan ethic in which the proper use of drugs is limited to medicinal use under the auspices of a physician. Notable exceptions are alcohol and tobacco. This ethic is gradually changing with the pendulum in contemporary values swinging forcefully towards permissivity of recreational drug usage. Marihuana has been established as a recreational drug of choice by many Americans.

8. Sociologic Considerations, Patterns of Use— The dramatic increase in marihuana use in the 60s continued less rapidly in the seventies. By 1974 approximately 1 of 5 Americans had tried marihuana with an estimated 50 million persons having direct involvement through 1976. Not every user likes the effect or continues its use; indeed, about 50% soon lose interest while chronic heavy use to some degree of incapacitation occurs in less than 2% of current users. The following trends are noted:

- (a) use is less frequent with increasing age with the crest occurring between 18 and 25 (over 50% of this population have used marihuana).
- (b) males outnumber females but the nearly identical frequency among the 12-17 age group suggests the gap to be closing.
- (c) the greater one’s education and socio-economic status, the greater the likelihood of marihuana use. A leading researcher, Goode, stated “the more uneducated one’s parents were, the greater the belief that marihuana use was harmful.”
- (d) the greater the parents use of legal substances, ie, tobacco, alcohol, prescription drugs, the more likely the offspring will use marihuana.

- (e) one's friendship network is highly related to drug use.
- (f) living in an urban area predisposes one to use
- (g) "liberal" social, political, and religious attitudes greatly increase the likelihood of use of marihuana (49% vs. 10% in one study).

One researcher observed that one could predict marihuana use nearly 100% based on only 4 factors—(1) sex (2) religiousness (3) political liberalism and (4) cigarette smoking. Thus of all non-religious, politically liberal, daily cigarette-smoking men, 97% had tried marihuana; of all religious, politically conservative non-cigarette-smoking women in the researcher's sample, only 4% had even tried marihuana and none used it weekly. In some subcultural groups within our society, marihuana is a taken-for-granted aspect of life. Within our own state, of about 16,500 individuals on probation, approximately 1200 involved possession of marihuana at an estimated state cost of \$200 per person per year. In 1974-75, of 2778 drug prosecutions, there were about 2 marihuana cases for every heroin case.

A brief survey sent to each of the 36 general and 23 psychiatric or specialty hospitals revealed rare admissions to the general hospitals for marihuana; the specialty hospitals reported a surprisingly high 139 (1974-75) admissions. Direct discussion with several medical directors of these facilities indicated that considerable treatment services were required for this group apart from the association of the patient with marihuana. It appears that admissions to general hospitals for marihuana use is nearly non-existent in Connecticut; diagnosis of marihuana abuse occurs relatively frequently but is *not* the primary factor requiring psychiatric treatment; clinical impressionistic reports is that marihuana has a *primary* contributing role in a small number of admissions to psychiatric or drug treatment facilities.

9. **Political Considerations**—Regardless of the scientific data, the political tone and individual decision-makers' needs exert a considerable influence on the actual shape of the law. The importance of age, sex, liberal vs conservative attitudes, use of cigarettes, legal drugs, etc. as mentioned influences objective law-making.
10. **The law**—In Connecticut, until 1967 (P.A. 555), selling and possessing were not distinguished. The judiciary had no alternative but to sentence a first offender to no less than 5 years, no more than 10 years, and a fine of up to \$3000. Our current law specifies that the 1st instance of possession of less than four ounces of marihuana carries a penalty of up to 1 year or \$1000 fine or both.
11. **Other Commission Findings**—There have been a number of major national and international re-

ports on marihuana beginning with the 7 volume Indian Hemp Study in 1893-94, including the La-Guardia study conducted by the New York Academy of Medicine, the U.S. and Canadian Commissions, and other major studies. Striking are the similar conclusions of them all:

- (1) possession of small amounts of marihuana, not intended for profit, for personal use should not involve a legal sanction that includes incarceration.
- (2) marihuana use carries certain risks; legalization is not recommended based on current knowledge.

The "Ideal Solution"

If there is a precise consistent and correct social policy on the use of marihuana, it has eluded the Committee—and apparently other state or national Commissions. An *ideal* potentially equitable solution is to legalize use of a substance according to the responsibility and maturity of the user as we do with a driving license. Individuals judged to qualify to use a specific substance responsibly would be so licensed. Such a method, in which we evaluate the responsibility of the user more than the potential danger of the drug, could remove the discrepant standards we presently apply to dangerous and potentially harmful drugs. The "double standard" with respect to alcohol and marihuana has been especially thorny. Most persons who use chemicals recreationally seem to do so responsibly; a minority does not. As with a driver's license, one must demonstrate certain knowledge and skill. Rather than stating that use of the drug alcohol is legal and use of the drug marihuana is criminal, the burden of responsible use is tied to the person. Unfortunately, our technology is still short of developing such a licensing device, and great problems are posed with respect to civil liberties.

Committee Recommendations

The primary recommendations of the Committee were:

- (1) There should be no change in the present Connecticut statutes with respect to sale of marihuana.
 - (2) The present penalties with respect to possession of less than 30 grams of the natural plant (excluding concentrates) for age 16 and over, for personal use, not intended for profit, for the first offense should be diminished and become a civil offense subject to a fine of not more than \$100.
- These recommendations were accepted after much debate by the Connecticut Drug Council and the recommendations have been endorsed by the Council of the Connecticut State Medical Society. The legislature in its 1976 session decided to maintain the current criminal statutes for simple possession.

SUPREME JUDICIAL COURT OF MAINE

Abdollah Gashgai, M.D.

v.

Maine Medical Association, Et Al

(January 19, 1976)

WERNICK, J.

This is an appeal by the defendants, Maine Medical Association, the Ethics and Discipline Committee of the Maine Medical Association and Bruce Trembly, M.D., in his capacity as Chairman of said Committee, from a Superior Court judgment embodying a permanent injunction against defendants.

The judgment was entered in a civil action against defendants instituted on May 10, 1974 by plaintiff, Abdollah Gashgai, M.D., a medical doctor duly licensed to practice medicine in the State of Maine and a member of the defendant Maine Medical Association. The complaint alleged that the Ethics and Discipline Committee of the Maine Medical Association, over the signature of its Chairman, Dr. Trembly, had issued a report concerning plaintiff and distributed it to

"a variety of individuals, institutions, bureaus and offices, in violation of the by-laws and procedures of Defendant Association."

The complaint also averred that the conclusions of the report

"... are so tainted by ... failure to accord due process that they have no basis in law or fact,"

and the actions of the Committee and its Chairman

"... are so arbitrary, capricious, discriminatory, willful, wanton and reckless as to cause irreparable loss and damage to Plaintiff."

Asserting that he would

"... suffer immediate and irreparable injury, ... unless said report ceases to be circulated and unless all existing copies are retrieved,"

plaintiff sought preliminary and permanent injunction prohibiting "... further circulation of said report" and commanding the parties who had sent or delivered the report to other persons "to retrieve all copies" sent or delivered.

After defendants had answered the complaint, the Justice held a hearing in June. On September 12, 1974, he filed findings of fact all of which are adequately supported by evidence and are, therefore, here controlling. These findings disclose the following factual situation.

On March 8, 1974 Mrs. Rayna B. Leibowitz, acting in her official capacity as a Medical Claims Consultant for the Department of Health and Welfare of the State of Maine, and in accordance with instructions given her by Dr. George Sullivan acting in his capacity as a

consultant to said Department and a member of the Board of Registration in Medicine of the State of Maine, forwarded to defendant Trembly, by letter, a request on behalf of the Department for an investigation by the Maine Medical Association Ethics and Discipline Committee of certain aspects of Dr. Gashgai's medical practice and conduct in specific instances. On March 25, 1974 Mrs. Leibowitz sent another letter providing supplement information and renewing the Department's request for investigatory assistance.

Shortly after March 8, 1974 Dr. Trembly, by telephone, and without indicating that charges had been lodged against Dr. Gashgai, requested that he appear on March 27, 1974 before a committee of the Maine Medical Association. At that time, Dr. Trembly did not further identify the committee. Subsequently, an undated letter was sent to Dr. Gashgai confirming the date and time of the meeting and informing Dr. Gashgai that a committee of the Maine Medical Association (still not more specifically identified) had been asked to look into the reasons for particular charges Dr. Gashgai had made to the Department of Health and Welfare.

Dr. Gashgai has been a member of the Maine Medical Association which (although a corporation) is, basically, a voluntary association of individuals licensed to practice medicine in the State of Maine. A condition precedent to membership in the Maine Medical Association is membership in a County Medical Society which is a component of the Maine Medical Association. Dr. Gashgai is a member of the Kennebec County Medical Society.

Dr. Gashgai honored the request of Dr. Trembly and appeared on the evening of March 27, 1974 in Augusta where he met informally with Dr. Trembly and other doctors who were members of the Ethics and Discipline Committee of the Maine Medical Association. It soon became apparent to Dr. Gashgai that the meeting had lost its original "conversational" tone and had become accusatory of him. It then dawned on Dr. Gashgai that Dr. Trembly and the others were actively engaged in investigating charges against him which were serious.

During a questioning of Dr. Gashgai lasting approximately two hours Dr. Trembly and the others on the Committee made references to invoices and other documents which had been provided to them by the De-

partment of Health and Welfare. They also utilized information contained in confidential documents supplied to the Committee, without Dr. Gashgai's prior knowledge or consent, by Dr. Henry J. Wheeler, Medical Director of the Augusta General Hospital. These same documents ultimately formed the basis of the conclusions reached by the Committee.

On March 27, 1974, without having undertaken any investigation additional to that constituted by the questioning of Dr. Gashgai on that date, the Committee issued a report containing the conclusions that the invoices submitted by Dr. Gashgai to the State Department of Health and Welfare showed gross overutilization, malpractice and unethical practice by Dr. Gashgai. The report also recommended that Dr. Gashgai be severely reprimanded.

The Committee sent the report to Dr. Gashgai and also to the Maine Medical Association, the Board of Registration in Medicine of the State of Maine, the Department of Health and Welfare of the State of Maine and the Medical Director of the Augusta General Hospital. As the result of having received the report, the Department of Health and Welfare placed Dr. Gashgai on a "constant surveillance" list, thereby requiring that all invoices henceforth submitted by Dr. Gashgai be carefully reviewed to evaluate the propriety of his charges.

The presiding Justice supported the permanent injunction issued by him¹ with the following conclusions: (1) the activities of Dr. Trembly and the other persons who had acted with him as members of the Committee on Ethics and Discipline of the Maine Medical Association were in violation of various of the Association's by-laws; (2) said activities contravened procedural due process requirements of the Constitutions of the United States and the State of Maine as applicable by virtue of the special relationship here existing between a governmental agency of the State of Maine and the Maine Medical Association and its Committee—a relationship sufficient to transform the Committee's activities into governmental action subject to constitutional due process mandates.

Defendants maintain on appeal that the findings of the presiding Justice of violations of the Association's by-laws and his references to the legal consequences flowing therefrom were not intended to be independently separate grounds of decision but were offered only as ancillary support for his constitutional due process conclusions. Defendants contend, therefore, that the only issue to be decided in this appeal is the correctness of the presiding Justice's holding that defendants' actions here in question are subject to the due process mandates of the United States and Maine Constitutions.

We disagree with defendants. Our study of the record convinces us that plaintiff had maintained before the presiding Justice that the violations of the Association's by-laws were discreet grounds entitling him to the injunctive relief sought by him independently of his additional claim of constitutional due process violations. The presiding Justice addressed each of these separate claims and concluded that each was a sufficient, independent ground justifying the injunctive relief he ordered.

We agree with the presiding Justice that the Committee actions of which Dr. Gashgai complains were in violation of particular by-laws of the Maine Medical Association and involved actual, and imminently threatened, injury to Dr. Gashgai—injury which was irreparable because it tended to impair Dr. Gashgai's opportunity to earn a livelihood through the practice of his chosen profession and, therefore, required the injunctive relief ordered. We sustain the judgment of the Superior Court Justice on this ground and do not reach the constitutional due process question.

The presiding Justice found that the Ethics and Discipline Committee of the Maine Medical Association had violated the Association's by-laws in three critical respects.² The presiding Justice then reached the conclusion of law that said

"actions . . . were a nullity under the Defendant Maine Medical Association's own internal rules."

The presiding Justice's findings as to the factual occurrences held to be violations of by-laws were adequately supported by evidence and are, therefore, here conclusive. The Justice's interpretation of the meaning of the by-laws, as applicable to the factual occurrences, was correct. Also correct was the presiding Justice's conclusion of law regarding the nullity of defendants' actions as a basis for judicial intervention to grant the injunctive relief here ordered.

Courts have relied on various rationales to justify their intervention to control the activities of private associations.³

For present purposes, since the by-laws of the Maine Medical Association here taken to be applicable are consonant with statutory and constitutional mandates and violate no general public policy of this State, they provide a proper basis for application of the "contract" rationale traditionally relied upon to justify judicial intervention to control the activities of private corporations. This Court recently utilized this "contract" approach, . . . holding that the by-laws of a private association

"provided they are not unreasonable, nor contrary to public policy nor to constitutional or statutory requirements, . . . [are] a valid enforceable contract between the members and the association . . . [which] govern their mutual rights and liabilities."

Thus, insofar as they here imposed obligations and restrictions upon the Association, the Association's by-laws are contractual terms cognizable, and enforceable, by a Court in accordance with the principles of contract law.

It is not material that the Department of Health and Welfare may have requested the Ethics and Discipline Committee to investigate particular facets of Dr. Gashgai's medical practice and conduct without knowledge of, or relation to, whether Dr. Gashgai was a member of the Maine Medical Association. The crucial point is that Dr. Gashgai was in fact a member of that Association. As such member, and specifically in reference to an investigation of his activities in the conduct of the practice of medicine undertaken by one of the standing committees of the Maine Medical Association in ostensible furtherance of purposes for which the Association exists, Dr. Gashgai was entitled to the protections afforded by the by-laws of the Association as the terms of a contract between the Association and him. Violations of the by-laws in the Association's dealings with Dr. Gashgai are thus breaches of contract specifically relating to Dr. Gashgai when he is legally entitled to remedy by resort to the Courts

As the United States Court of Appeals for the District of Columbia Circuit stressed in *Marjorie Webster Junior College, Inc., v. Middle States Association of Colleges and Secondary Schools, Inc.*:

"The increasing importance of private associations in the affairs of individuals and organizations has led to substantial expansion of judicial control over 'The Internal Affairs of Associations not for Profit.' Where membership in, or certification by, such an association is a virtual prerequisite to the practice of a given profession, courts have scrutinized the standards and procedures employed by the association notwithstanding their recognition of the fact that professional societies possess a specialized competence in evaluating the qualifications of an individual to engage in professional activities. . . .

" . . . the extent to which deference is due to the professional judgment of the association will vary both with the subject matter at issue and with the degree of harm resulting from the association's action."

See also: *Falcone v. Middlesex County Medical Society*, 34 N.J. 582, 170 A.2d 791 (1961).⁴

The judgment of the Superior Court is affirmed.
Appeal denied.

REFERENCES

1. The Justice (1) prohibited the " . . . circulating, forwarding or distributing the report of the . . . Committee dated March 27, 1974 as

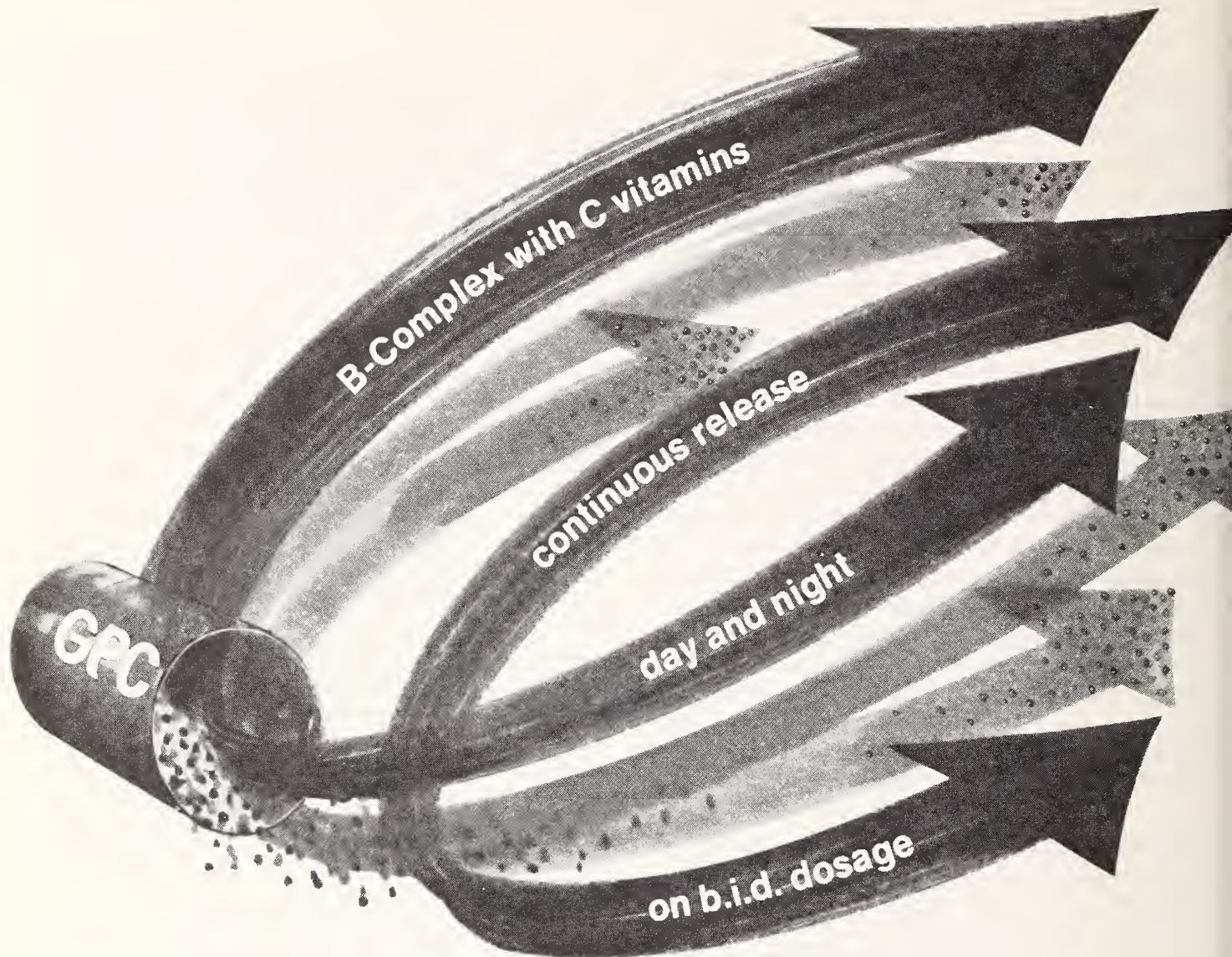
it pertains to plaintiff, and" (2) ordered that each of the defendants, except for their attorneys of record, " . . . expunge from their records said report and any references thereto, that copies of this Order and the Findings of Fact and Decree of . . . [the] Court be sent by Defendants to each person or organization to whom the original report was sent, and that all copies of said report now in the hands of defendants or within their control, now or in the future, except one copy in the hands of defendants' attorneys of record, be finally and permanently suppressed."

2. These by-law violations were: (1) "The By-laws of the Defendant Association provide that the Defendant Committee shall urge disposition of ethical complaints at the local County Society level, by County Society officers. Defendant Trembly and the Defendant Committee made no effort to refer the complaint of the Department of Health & Welfare in Plaintiff's case to the appropriate Component Society, the Kennebec County Medical Society." (2) The Ethics and Discipline Committee wrongly undertook the *investigatory* tasks involved in the requests made to it by the State of Maine Department of Health and Welfare since "[t]he By-laws of the Defendant Association provide that the Defendant Committee shall have 'no power or authority' to act upon any complaint or claim or case referred to it where the facts of the complaint are or may become the basis for an action in tort against the doctor whose conduct is being investigated until and unless any case which should arise is finally disposed of." (3) The Ethics and Discipline Committee wrongly undertook the *investigatory* tasks involved in the requests made to it by the State of Maine Department of Health and Welfare since "[t]he By-laws of the Defendant Association provide that the 'primary duty' of the Defendant Committee is to give careful consideration and study to methods and practices which tend to eliminate justifiable complaints against the profession or individual members of the medical profession on the desirability of following those recommended methods and practices."

3. Harv. L. Rev. 983, et seq. contains an extensive review of the matter in its evaluation of "Developments in the Law" concerning "Judicial Control of Actions of Private Associations."

4. In *Falcone* the Court made the cogent observation: "When courts originally declined to scrutinize . . . practices of membership associations they were dealing with social clubs, religious organizations and fraternal associations. Here the policies against judicial intervention were strong and there were no significant countervailing policies. When the courts were later called upon to deal with trade and professional associations exercising virtually monopolistic control, different factors were involved. The intimate personal relationships which pervaded the social, religious and fraternal organizations were hardly in evidence and the individual's opportunity of earning a livelihood and serving society in his chosen trade or profession appeared as the controlling policy consideration."

EDITOR'S NOTE: *Except for deletion of several paragraphs not relevant to the main issue, and minor editorial changes and omission of some legal references, the wording in this decision is that of the court. The case is instructive in pointing out that the legal relation of a member to his county and state societies is a contract. Accordingly, it is necessary to adhere to the bylaws of the Society. Though it is obvious that the accused physician did not receive procedural due process, the courts felt they did not need to "reach the constitutional due process question." In order for the Society to pass judgment on the charges against the physician, it will be necessary for it to start its proceedings from the beginning, following the bylaws of the Society, and also to insure that in adjudicating the case it accords the accused physician a fair hearing conforming to the courts' interpretation of due process.*



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Connecticut Hospital Association Manual on Informed Consent*

John Q. Tilson, Esq. and J. Michael Eisner, Esq.

Introduction

This is a "Manual on Informed Consent" for Connecticut Hospital Association member hospitals. CHA emphasizes that it is not possible to develop one policy which will meet the special needs of each hospital, nor is it possible to develop a policy which will guarantee that informed consent will be obtained from or on behalf of every patient who undergoes a surgical procedure or a procedure involving risk. It is essential, however, that "informed consent" be obtained, and it is recommended that consent be recorded on a form which is signed by the patient or the person giving consent.¹ Furthermore, it should be made clear to the Medical Staff that it is the responsibility of the physicians to see to it that "informed consent" has been obtained.

This manual is not intended to set legal standards for the obtaining of informed consent, nor is it intended to shift the burden of obtaining consent from the physician, whose duty it is to obtain consent, to the hospital.

The law of informed consent has been developing rapidly. Therefore, each hospital's consent policy should be reviewed from time to time by its legal counsel.

Informed Consent Must Be Obtained Except in the Event of an Emergency.

Except in the event of an "emergency" (refer below to discussion of "emergency"), the physician must obtain the "informed consent" of the patient (or of the person giving consent if the patient is unable to consent) before he performs any invasive procedure or other procedure involving any degree of risk to the life or well being of the patient. Consent should be obtained, for example, for all inpatient and outpatient

operative and manipulative procedures, radiation therapy, and whenever, in the judgment of the responsible physician, the situation or nature of the procedure, or risk, warrants that written consent be obtained. While the traditional view was that a physician has a duty to disclose such information as is customary in the community in which the physician practices (and in Connecticut the "community" has been defined as being the entire state), the more modern rule is that the patient is entitled to whatever information a reasonable patient could be expected to receive in order to make an informed determination as to whether or not he would consent to the procedure. The test is not whether the patient would have consented to the operation in light of the information, but whether a reasonable person having in mind all of the facts would or would not have consented. Connecticut physicians should act on the theory that the modern rule will prevail. They should, therefore, take it upon themselves to make full and frank disclosure to the patient of all information which the patient can reasonably be expected to need in order to make a rational decision.

Definition of "Emergency"—The existence of a medical emergency has been held by the courts to obviate the need for any consent. It is essential, however, that the patient's condition justifies acting without consent and that the beginning of treatment cannot be delayed for consent to be obtained. A simple definition of an "emergency" would be a situation posing a significant threat to the life or health of a patient. It would be advisable for the attending physician to seek consultation before acting. The fact of the emergency and the opinion of the consultant should be documented and included in the patient record. The consultant's report should show evidence of a review of the patient's record by the consultant, pertinent findings on examination of the patient, and the consultant's opinion and recommendations.

The Physician's Responsibility for Obtaining Informed Consent

It is the physician's responsibility to obtain the informed consent of his patient or, when the patient is not capable of giving his informed consent, the substituted consent of the parent, guardian or other person acting in place of the patient. Where the physician believes without any reservation that a nurse or other qualified person, such as a qualified technician, can

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*APPROVED: Connecticut Hospital Association, Board of Trustees, October 18, 1976.

1. This manual is not intended to require a hospital which does not use consent forms to use such forms, or to suggest that the mere use of a form conclusively establishes that informed consent has been obtained.

Editor's Note—Also, this manual is not intended to represent or be the standard or official statement on Informed Consent of the Connecticut State Medical Society.

properly perform the job of obtaining informed consent, the physician may delegate the task. The physician, however, not the nurse, will continue to be responsible for obtaining consent. The physician should delegate this task of obtaining consent only where (1) the procedure is routine, (2) The risk is low, (3) he is personally satisfied that the nurse will perform the task properly, (4) the nurse always is acting under his supervision, and (5) he will be available for consultation if the patient has any questions. Where the nurse or other qualified person is to obtain consent, he or she should be required to tell the patient that the physician is available to answer questions upon request.

Where the physician personally has obtained the consent, there is no reason why a responsible aide may not be in charge of securing the patient's signature on the consent form. The form, of course, will be worthless unless the physician has obtained informed consent and the form accurately reflects this fact.

*Responsibility of the Hospital and Committees of the Medical Staff**

As emphasized above, it is the physician's responsibility to obtain informed consent. The hospital, however, may wish to implement procedures which will facilitate the physician's job of obtaining consent. The Chief of Staff or the Chief of Service, for example, might, if possible, delegate to responsible non-physician personnel the job of checking to see that consent has been obtained, reduced to writing, and placed in the patient record prior to the performing of the procedure. It should be the responsibility of the medical records department to ensure that records are complete with respect to consent and to take appropriate action when the hospital's consent policy is not being followed. The medical records committee also should see to it that adequate documentation of consent is being included in patient records and should take appropriate disciplinary action against physicians whose records are incomplete.

What Information Must Be Given by the Physician to the Patient or the Person Giving Consent in Order That Informed Consent is Obtained?

The purpose of consent is not to frighten the patient but to give him enough information to enable him to make an intelligent decision in regard to treatment. Obviously, a physician does not have to disclose hazards that he cannot be expected to know about. Nor

does he have to disclose hazards which occur so very rarely that no reasonable person would consider them a hazard at all. On the other hand, he does have to disclose both dangers and alternatives. There is a fine line, of course, as to what constitutes a danger. If an event occurs once in ten times, every court would undoubtedly consider it a hazard that should be revealed. If, on the other hand, it happens once in ten thousand times, the decision would probably be different. In one well known case, it was held that the physician was liable for failing to disclose a one per cent risk of paralysis as a result of a laminectomy. In between these extremes is a gray area in which the courts are struggling in an attempt to assure the patient that he gets all the information that any reasonable person could be expected to get and at the same time to furnish some slight protection to the doctor that he will not be second guessed on the issue of consent in any situation where the results turn out to be less favorable than the parties might have hoped.

Information provided to the patient should include discussion of benefits, risks, and alternatives. For example:

- (1) the physician's diagnosis and prognosis;
- (2) the suggested procedure, its purpose, and a brief description of what it involves;
- (3) the chances of success or failure of the contemplated procedure;
- (4) alternative methods of treatment or the possibility of nontreatment, and the prognosis for such alternatives or nontreatment;
- (5) an evaluation of the risks and benefits of the contemplated procedure.

Additionally, the physician should advise the patient that he is available to answer any questions which the patient might wish to ask. Throughout the course of informing the patient, the physician should strive to use language which the patient understands and should satisfy himself that the patient is satisfied that his questions have been answered.

In summary, the physician is not required to give a course in medicine, but he should be sure that the patient understands what he is saying and is willing to undergo the procedure in spite of the risks.

Consent Forms

The hospital which chooses to use forms might continue to use its present forms, or choose one of the two sample forms annexed hereto. The choice of form is left to the hospital because in CHA's view the matter of the form is comparatively unimportant. A form merely records the fact that consent was obtained. The burden of establishing consent is thereby eased, it being the patient who subsequently must explain why,

*It should be recognized that while the procedure outlined in this section may be helpful, it raises the possibility of a claim that the hospital has a duty to obtain consent which is independent of the physician's duty to obtain consent. Accordingly, use of this type of procedure should be carefully considered before it is implemented.

in spite of his having signed the form, his informed consent was not given.

CHA does recommend that separate forms be used for abortion and sterilization (refer to discussions below).

Form I is a "short" form. It specifies the procedure to be performed and authorizes the physician to take whatever steps seem necessary to carry it out. It furnishes evidence as to the operation or procedure performed and secures the patient's signature on a piece of paper which indicates that consent was given. The form has the advantage of simplicity. It does not increase patient anxiety. It has the disadvantage of not disclosing what hazards were spelled out to the patient. Obviously, if this type of form is used, the patient is going to be able to introduce evidence to the effect that various hazards were not explained and that had the hazards been spelled out, the form would not have been signed.

Form II is a "long" form and has the obvious advantage that it spells out certain hazards. If the physician or hospital is lucky enough to have one of the hazards which is described on the form be the hazard which does occur, the hospital and physician will be better off than if Form I had been used. On the other hand, even where the long form specifically sets out the hazards which are involved, there are risks to the defendant hospital in that the patient can say that the forms were obtained either when the patient was not capable of knowing what he was signing or the information set out in the forms was not in fact given.

As stated above, it is our essential belief that the matter of the form is comparatively unimportant. Obviously, long forms will be better if, in fact, the physician does sit down with the patient and does disclose all of the things the form says he discloses. If, however, the dealings between the physician and the patient are minimal but the long form nevertheless is routinely completed, then the use of such a form creates as many problems as it solves. If, for example, the form discloses five hazards and the patient sustains injury from a sixth, the defendant is going to be hard put to establish the fact that the sixth hazard was in fact disclosed. In our opinion the important thing is to get the attending physician to take the time to sit down with the patient and spell out the nature of expected hazards. If this is done, the nature of the form used becomes relatively unimportant. In the final analysis, there is no substitute for a close relationship between the physician and the patient.

The above discussion deals with two types of consent forms. A number of hospitals use additional forms for other procedures. On the whole, we recommend against a proliferation of forms and suggest that one or the other of the forms referred to above can be

adapted to use under most conditions.

General Consent Forms

CHA does not suggest the use of a general consent form to be signed at the time of admission. We recognize, however, that a number of hospitals do require that the patient sign a general consent form upon admission. There is nothing wrong with such a practice, but we question whether it is particularly helpful. It certainly will not preclude the subsequent necessity of the physician giving an adequate explanation to the patient and obtaining his informed consent.

The Medical Record

In addition to the use of a form, it is suggested that a notation be made on the medical record that the procedure and its alternatives, if any, have been discussed with the patient or the person giving consent, and that informed consent has been obtained.

Persons from Whom Consent Should Be Obtained if the Patient Is Not Capable of Giving His Informed Consent

If the patient is incapable of giving consent, and there is no emergency which obviates the need for consent, then "substituted consent" must be obtained. The person who is to give such substituted consent should be as fully informed as the patient would have been if capable of giving consent. The usual situations requiring substituted consent are those involving minors and patients unable to consent because of their physical or mental condition.

Minors—As a general rule, consent should be obtained from the parent or legal guardian. Under certain circumstances, however, consent may be obtained from a minor without parental consent or consent from a guardian or other person acting *in loco parentis*. Section 19-142a of the Connecticut General Statutes provides that "(a)ny minor who has been married or who has borne a child may give effective consent to medical, dental, health and hospital services for his or her child." Secondly, there is the "emancipated minor" who can give effective consent to medical treatment. Ordinarily, a minor is considered to be emancipated if he is economically separated from his parents. If, therefore, the minor who is living alone is supporting himself, he presumably would be considered to be emancipated. Also, a married minor usually would be considered to be emancipated. Additionally, there is no age limit in cases involving drugs or venereal disease, and the age limit is sixteen in cases involving admission for mental illness provided that the patient has applied in writing for observation, diagnosis or treatment of a mental disorder.

There is another doctrine which may be of assistance to hospital personnel who have to face the situation of trying to decide whether to go ahead without parental consent where there is no "emergency" and where the minor is not emancipated. This is the so-called "mature minor." The judgment which can be exercised by an individual obviously does not change between the day preceding and the day following his or her eighteenth birthday. The law makes a person an adult at age eighteen, but there are various situations, set forth above, in which a person under that age may give consent. It is certainly preferable to try to get parental consent in all cases where the patient is under eighteen (except in cases involving drugs and venereal disease), but in situations where parental consent is not readily obtainable and the patient appears mature enough, it may very well be possible to take his or her consent. CHA counsel knows of no case where a hospital or physician has been held liable where the patient appeared to be mature but was under the statutory age limit.

In the event that parental consent cannot be obtained and the minor is not emancipated, care should be taken to document the circumstances, including the medical situation and efforts to contact members of the family. In case of any doubt, it probably would be helpful if at least two physicians participated in the decision to go ahead, and such consultation was duly recorded in the record. As aforementioned, the consultant's report should show evidence of a review of the patient's record by the consultant, pertinent findings on examination of the patient, and the consultant's opinion and recommendations.

Patients Unable to Consent Because of Their Physical Condition

If the patient is unable to consent because of his physical condition, e.g., he is comatose, then substituted consent should be obtained from a close relative.

There is no Connecticut law as to the order in which relatives have the right to consent. It is suggested, however, that the hospital follow the formula set forth in the Anatomical Gift Act (19-139d) which lists the order of consent as: (1) spouse; (2) adult son or daughter; (3) parent; (4) adult brother or sister. If none of the above are available and if the patient has no duly appointed conservator of the person, it is advisable that the hospital take the consent of anyone who appears to be in a position of taking care of the patient, e.g., a friend or a more distant relative.

Psychiatric Patients—A voluntary patient who does not have a conservator of the person or a legal guardian undoubtedly can give valid consent to

surgery or other medical procedures not related to his mental condition unless, in the opinion of the physician, his mental condition is such that he does not understand the nature of his illness or the treatment involved. Medical or surgical procedures involving an involuntary patient require the written informed consent of the patient's guardian, next of kin or court-appointed physician.

Abortions

Consent ordinarily should be obtained from the patient, or, where practicable, the patient and her parent or legal guardian if the patient is an unemancipated minor. Where consent of the parent or guardian cannot be obtained, the matter should be referred to the chief of service who should determine whether or not the procedure should be performed. At the discretion of the chief, special cases should be reviewed with an administrative officer of the hospital. When the procedure is authorized by the chief, his written approval and the patient's written consent should be incorporated into the medical record. There is no need to obtain the consent of the spouse although in cases of known disagreement the hospital may wish to provide counseling. In the case of abortions which are to be paid for by the State Department of Social Services, the parent or guardian, or the Commissioner of the Department of Children and Youth Services in the case of a committed child, must give written consent in order to obtain Title XIX (Medicaid) reimbursement.* The hospital also should be familiar with the State Health Department's abortion regulations, section 19-13-D54 of the Public Health Code, which require, *inter alia*, pre-operative counseling. Under no circumstances should an abortion be performed when the patient refuses to give her consent.

Sterilizations

Form IV, "Permission for Sterilization" is attached hereto. Note that the Department of Social Services has issued its sterilization consent form which must be used before the Department will make any payment for the procedure.

In the opinion of CHA counsel, there is no need to obtain the consent of the spouse. However, it obviously is extremely important that the patient understand that the procedure will render her or him incapable of having children.

Although the state may obtain the sterilization of certain of its wards pursuant to special statutory procedures, it is the opinion of CHA counsel that at the present time it is extremely difficult to secure an

*The constitutionality of this requirement is subject to test in the federal courts.

effective consent to a nontherapeutic sterilization of an incompetent (including minors). In cases where such a procedure is proposed, the case should be referred to hospital legal counsel.

Transplants and Tissues

In cases of transplants involving donations of body tissues by minors, the matter should be referred to hospital legal counsel. It will be necessary, except perhaps in the case of a mature minor whose parent or legal guardian is also willing to consent to the donation, to secure a court order declaring the right of the parent or guardian to consent to the donation.

Donations by incompetents should not be considered except under extraordinary circumstances and after consultation with counsel.

Consent also must be obtained to use retained tissue. Tissues removed and retained with consent are the property of the hospital. Form I contains the following general authorization:

I also authorize the Hospital to preserve for diagnostic, scientific or teaching purposes or otherwise dispose of the tissue, specimen or organs resulting from the procedure authorized above.

If tissue is to be used for some other purpose, authorization from the patient should be secured.

Intoxification Tests

If a person is brought to the hospital by the police pursuant to the Treatment of Alcoholics and Intoxicated Persons Act, the medical officer may conduct a preliminary examination for the purpose of deciding whether the person examined is incapacitated by alcohol notwithstanding the fact that the patient objects. However, the results of such an examination may not be turned over to the police without the consent of the patient (who should be presumed incapable of giving such consent while incapacitated or intoxicated.) No other tests should be performed at the request of the police unless the patient consents to the tests. While all medically necessary tests should be performed for the benefit of the patient, no test should be performed for the police if the patient is unconscious or otherwise incapable of giving his consent.

Jehovah's Witnesses

The standard rule is that a competent adult patient has a right to refuse to consent to any medical procedure and that if the hospital or physician proceeds in spite of such refusal there is a risk of litigation involving assault and battery.

It is emphasized that the decision must be that of the patient, not his next of kin. Therefore, if the patient is a minor or for other reasons is not capable of consenting or refusing to consent to transfusion, the

hospital may not merely rely on the refusal of his next of kin.

In the case of a child under sixteen, the hospital should petition Juvenile Court and seek a declaration that the child is neglected and an order directing the hospital to administer the transfusion. For unemancipated sixteen and seventeen year olds, jurisdiction would lie both in Probate and Superior Court. CHA suggests going to Probate Court. Parental rights would be temporarily suspended and temporary guardian appointed who could consent to the transfusion. It is suggested that the hospital work out procedures with local courts in advance.

In an emergency, the blood may be given to a minor without consent. Adequate documentation should be placed in the medical record, but there is no need to petition the court. The law is, as aforementioned, that an emergency obviates the need for consent.

In the case of an adult, the hospital should obtain a written release from the patient or from the next of kin. In rare circumstances (for example, where there are minor children or where the patient is young and would have a good chance of recovery with transfusion), the hospital or physician may feel so strongly on the subject that an attempt may be made to secure an injunction in the Superior Court. Chances of obtaining an injunction are not very good where the patient is an adult with no minor children. The chances would be improved if the patient had minor children. In any event, since injunction proceedings can be time consuming, the time element might be such as to preclude the possibility of legal proceedings. Nevertheless, if the patient has minor children, serious consideration should be given to an attempt to secure a court order no matter how pressing the time element may be.

Experimental and Research Procedures

This memorandum does not deal with the problem of consent to experimental or research procedures. Such procedures require special forms and hospital counsel should be consulted.

Medical Staff Bylaws and Rules and Regulations

CHA sees no need to specifically refer to the question of consent policy in the Medical Staff Bylaws. Where appropriate, however, the hospital should make reference to its consent policy, and the duty of the physician to obtain informed consent, in the Medical Staff Rules and Regulations. For example, Model Rule C 1 of the The Guidelines for Medical Staff Rules and Regulations prepared by the Joint Commission on Accreditation of Hospitals provides that:

A general consent form, signed by or on behalf of every patient admitted to the hospital, must be obtained at the

time of admission. The admitting officer should notify the attending practitioner whenever such consent has not been obtained. When so notified, it shall, except in emergency situations, be the practitioner's obligation to obtain proper consent before the patient is treated in the hospital.

We do not advise the adoption of the model rule, but do suggest that the hospital briefly describe its consent policy in the rules and regulations of the medical staff. It is further suggested that a statement be included to the effect that "It is the practitioner's obligation, except in emergency or extenuating circumstances, to obtain the informed consent of the patient or of the person giving consent on behalf of the patient in accordance with the hospital's consent

policy before the patient is treated in the hospital."

Conclusion

It is CHA's recommendation that each hospital develop its own policy on informed consent in light of its particular needs and desires, and in consultation with its own counsel.

It is emphasized that even the best policy will not prevent claims that proper consent was not obtained. Hopefully, however, a carefully drafted policy which is adhered to by the medical staff and is kept current in light of changes in the law will reduce the number of such claims and enable the hospital to successfully defend itself against the remaining claims.

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The Connecticut Commission on Hospitals and Health Care

Dick Howard and James E. Jarrett

Foreword

The policy, management, and operations of state government require the application of constantly updated approaches to address changing needs and priorities. This necessity for self-renewal implies innovations in the institutions of state government, in their structure, policies, procedures, and personnel.

Many innovations have occurred in recent years in a number of fields at the state level. However, too little is known about some specific state activities because of the variety of laboratories in which they occur. The innovations process is further complicated by the fact that state government officials rarely have the time or opportunity to share such knowledge which may be applicable in other States. Under day-to-day pressures and constraints, professional administrators and technical experts lack the time to document or otherwise share new approaches they have developed.

The Council of State Governments, which has been providing a forum for such an exchange for many years, has recently expanded its efforts in this area. The Connecticut program to control health costs is one of six innovative state efforts being studied by the Council under a grant from the National Science Foundation. Other programs selected for review include statewide tax assessments, railroad branch line rehabilitation, pension fund consolidation, maximizing interest income on state investments, and energy management and development.

Brevard Carihfield, Executive Director
The Council of State Governments
Lexington, Kentucky, March 1976

Preface

Americans are now spending more than \$100 billion a year for medical care, and as is well known, the costs are skyrocketing. The Consumer Price Index shows that from 1960 to May 1975 the increase was 118 percent (the index moved from 79.1 to 166.8). A major cause of this rise is hospital costs. The Department of Labor's Consumer Price Index shows an increase in costs for a semiprivate room of 402 percent, from an index of 57.3 in 1960 to 230.1 in 1975.

Little wonder that in October 1975 Policy Positions, the National Conference of State Legislatures: "Urges state legislators to examine and evaluate for possible adoption the various alternative legislative and administrative actions available for moderating the rapid increases in hospital costs, including controlling unnecessary construction, controlling hospital rate increases, providing incentives for efficiencies in operation, and changing insurance regulations to affect health care utilization."

Likewise, the National Governors' Conference

This report on Connecticut's program to control health costs was prepared by Dick Howard, Director of the Council's Innovations Project, and James E. Jarrett, Research Associate, The Council of State Governments.

"urges the States to enact needed planning and regulatory legislation."

This study describes health cost containment programs in three States. Their experiences suggest they are making some progress in limiting the rise in medical care costs. These three States have chosen to intervene directly by regulating hospital rates. Obviously, this is not a solution all States will pursue for both philosophic and administrative reasons.

Opponents of state regulation in the health field believe regulation inevitably leads to political influence and bureaucratic inefficiency, that it favors the status quo impeding development of more efficient facilities and programs. Advocates maintain that because of special conditions affecting supply and demand in the health care industry, including minimal price competition, the public interest can best be served through regulation.

The issues are complex, the economic stakes substantial, and the political pressures are considerable. This report describes the Connecticut, Maryland, and New Jersey approaches in such a way that legislators and officials in other States can determine if such programs might be useful in their States. At the request of the Council of State Governments (CSG) innovations advisory panel, the Connecticut Hospital and Health Care Commission (CHHC) was selected for major emphasis since at the time of selection, more information was available about Connecticut's program.

Further information can be obtained from the health cost review agencies in Connecticut (phone no. 203-566-3880). The Council of State Governments (phone no. 606-252-2291) is also prepared to provide additional information assistance.

The Commission on Hospitals and Health Care is a 15-member regulatory body authorized to act in partnership with the administrators and trustees of all nongovernmental health care institutions and facilities within the State in the provision of high quality health care for the citizens of Connecticut at the lowest possible cost.

In one of its regulatory functions, the commission, serving as the State's Comprehensive Health Planning "A" Agency and in conjunction with the State's 11 areawide Comprehensive Health Planning "B" agencies, carries out a continuing health care utilization review in an effort to improve efficiency and reduce costs. In another of its regulatory functions, the commission is the "certificate of need" authority for all capital expenditures in excess of \$25,000 proposed by any health care facility. The commission also has authority to review and approve or deny any health care institution's proposal to increase charges in excess of 2 percent per annum. It also has the power to review and grant or deny any additional function or service a health care facility within its jurisdiction may propose.

Background

Connecticut has a well developed medical delivery system. Its 35 acute care health facilities are scattered over the State so that all of the State's citizens have good access to health facilities. It is reported that there are 68 hospital beds per 10,000 people, compared to 45 for the Nation. Table 1 presents a profile of the Connecticut health system.

Table 1

	<u>CT</u>
Short-term (nonfederal) hospitals	35
Hospital beds, per 10,000 population	68
Nursing & related care homes	365
Physicians per 10,000 population	20
Average daily hospital costs	\$149

Hospital costs in Connecticut and nationwide have risen dramatically in the past decade. During the two-year period, 1969-71, costs rose 33.3 percent. In 1972 costs rose another 12.5 percent and 11.2 percent in 1973. A political issue was born. Activity that led directly to the Connecticut Commission on Hospitals and Health Care (CHHC) began in 1968 when then Governor John Dempsey, a Democrat, appointed a blue ribbon commission to look at spiraling hospital costs. A member of that commission, Dr. Morris Cohen, a state representative, subsequently concluded that a "public utility type" commission was one answer to Connecticut's rising health costs. After a year of hearings conducted by the joint Committee on Public Health and Safety chaired by Dr. Cohen, legislation was introduced in 1971 to create a health cost commission. The bill failed. It failed again in 1972. As if to prove that politics does indeed make strange bedfellows, Democrat Cohen worked with Republican Governor Thomas Meskill in establishing a health cost commission, and in 1973, PA-73-117 was enacted creating the CHHC.

Political Factors

Opposition to the Connecticut commission was considerable and was led by the Connecticut Hospital Association, Dr. Cohen recalls. The opposition included massive letter writing campaigns and newspaper advertisements. Support for the CHHC came from senior citizens groups, labor unions, and consumer groups. For the most part, Blue Cross and the private insurance carriers did not take sides in the struggle, although they were not opposed to the idea.

Support and opposition to health cost review seemed to hinge on economics. The difference between what Blue Cross pays and what other carriers pay in Connecticut is slight. The hospitals did not see the law as an opportunity to increase reimbursement for costs, but rather as creating a vehicle that might reduce overall revenues by lowering hospital charges.

The Connecticut Hospital Association was especially fearful that the cost commission could require cost reductions in specific activities of member hospitals, for example, salaries, food services, and laundry.

Through the legislative process, the chief modifications to the Public Health and Safety Committee bill were the elimination of certain health related qualifications for the position of executive director and elimination of a proviso that would permit the commission to examine hospital costs on a line-by-line basis.

Brief Chronology

The CHHC officially began operations October 1, 1973. The Comprehensive Health Planning "A" staff was transferred from the Health Department to the new commission. The rate analysis section of the Hospital Cost Commission (established in 1949 to review hospital costs and terminated September 30, 1973) was also transferred to the CHHC. Thus, the CHHC was established requiring few additional state employees.

Republican Governor Meskill left office in January 1975 and the CHHC executive director resigned at about the same time. As of January 1976 the commission had not appointed a successor.

In 1975 the Legislature transferred the CHHC staff to the Health Department for purposes of administration (Public Act 75-562). Certain regulatory components of Connecticut's Emergency Medical Services Program that had been assigned to the CHHC also were transferred to the Health Department in 1975 (PA 75-112).

Major Legal Provisions

The Connecticut Commission on Hospitals and Health Care is codified in Chapter 334a, Sections 19-73a through 19-73t. The law is specific in the composition of the commission, how it shall regulate costs, the requirement for hearings, and time frames to be used.

The chief provisions are summarized:

- (1) All hospitals and such other health care facilities as the commission designates must submit annually their proposed operating and capital expenditures budgets to the commission for review.
- (2) The commission must hold public hearings and approve, disapprove, or modify any hospital proposals to change services charges by more than 6 percent over a 12-month period or 10 percent over a 24-month period; or nursing home rate increases of 4 percent over a 12-month period or 6 percent over a 24-month period.

- (3) For proposed rate increases of 2 percent or more, but less than that shown above, the commission may or may not require a public hearing.
- (4) Health care facilities or institutions proposing capital expenditures of \$100,000 or more require commission approval and public hearings; proposals for expenditure of \$25,000 to \$100,000 require commission approval, but not necessarily public hearings.
- (5) The commission may make regulations to carry out its duties and carry out a continuing statewide health-care facility utilization review.
- (6) The commission has the authority to conduct investigations and subpoena power.

Organization

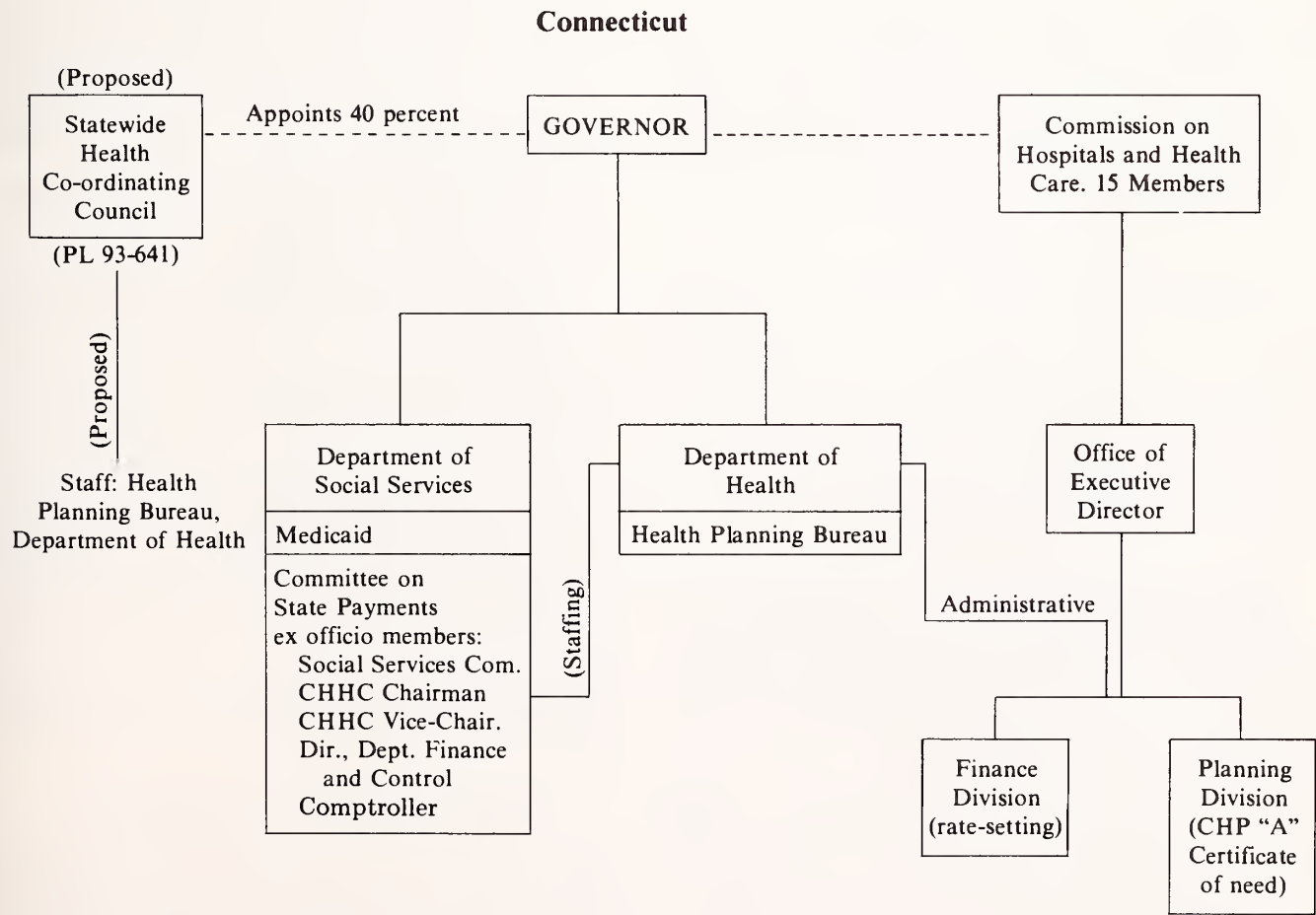
The figure shows the present organization of health cost review and health planning in Connecticut. In addition, it provides a look at the organization of the commission being examined here.

The Connecticut commission consists of 15 persons. The statute is specific about who appoints them, their terms, and the consumer/provider mix. There are three ex officio members—the commissioners of

health, insurance, and mental health. Two public members are appointed by the speaker and the senate president pro tem and the terms of these members coincide with those of the appointing authorities. The other 10 members are appointed to five-year staggered terms by the Governor. One must be a practicing registered nurse, and three other health care provider members are selected from nominations of the Connecticut Hospital Association, Connecticut State Medical Society, and the nursing home industry. The remaining six gubernatorial appointees must not be associated with the health care industry. The Governor selects the chairman of the commission.

The commission selects the executive director who serves at the pleasure of the commission. The executive director is the only staff member who is not part of the state civil service. Organizationally, the commission staff is divided into two operating units, the planning division and the health care finances division.

The planning division consists of seven individuals including the deputy director for planning. The planning division is responsible for the certificate of need determinations under Connecticut law, and this means that the division must be involved in making



recommendations and setting up public hearings to review proposed capital expenditures. Other major functions of the planning division include developing a comprehensive health plan for the State and providing staff for the several task forces studying health delivery problems.

The Division of Health Care Finances consists of four professionals (1/76) although it has authority for six.¹ The division's chief functions are monitoring and reviewing costs and rate schedules of nongovernmental health care facilities. Its present organization calls for four staff members assigned to budget and rate review and two to cost analysis. Each year the budgets of all hospitals must be reviewed and rates set. This staff assists the commissioners throughout the public hearings and decision-making process.

The health care finance division plans to establish a field auditing section and a management auditing section. As noted earlier, both the health planning division and the finance division are under the administrative control of the State Department of Health.

The Commission on Hospitals and Health Care is supported from state general revenue and federal funds. In the 1974-75 fiscal year its operating budget was \$479,140 of which \$159,000 was federal money. The 1975-76 operating budget was reported as being approximately \$417,000, including \$137,000 of federal funds. In response to an HEW "request for proposal," the CHHC is submitting a proposal to the federal government that calls for \$600,000 annually for three years. That proposal also would facilitate the CHHC's planned use of Blue Cross for data processing and computer programming.

At present, the Connecticut CHHC has most of the "health organization pieces" it needs to perform its duties. The forthcoming federally mandated Statewide Health Coordinating Council (Public Law 93-641) will necessarily confuse the situation from the viewpoint of the CHHC. It is not clear what will become of the CHP "A" agency which now is responsible for the certificate of need program.

Cost Containment: The Process

The commission's approach to cost containment is multifaceted. Commission responsibilities are extensive including decision-making authority over capital expenditures and annual operating budgets as well as reviewing rates and analyzing costs.

According to an assistant attorney general's opinion, the commission's decision-making powers cover all nongovernmental health care and health-related facilities, as defined by the commission, in Connecticut. Because of its extensive legal authority the main limitation to the commission's tasks has been insuf-

ficient staff. To keep the workload manageable, the commission initially limited its duties to annual budget reviews of hospitals, review of price increase requests from nursing homes and other long-term care facilities, and review of capital expenditure proposals from hospitals and long-term care facilities.

The Hearing Process

Every major decision of the Connecticut commission is reached only after consideration of the views of the affected institution and the public. Because the hearing process is an integral part of the cost containment process it is included here in some detail.²

- (1) For capital expenditure proposals, the process begins with receipt of a completed application although staff usually had contact with the sponsor prior to formal submission.
- (2) From the full commission, three commissioners are selected (usually by expressing interest in the general issue area or by signing up for a specific hearing) to sit as a hearing panel.
- (3) There is a site visit (for capital expenditure proposals only) which may be attended by the commissioners, staff, or representatives of local health planning agencies depending on the size and importance of the proposal.
- (4) A hearing date is set. At the hearing, conducted under Connecticut's Administrative Procedures Act, the sponsor's proposal is examined in detail by staff and commissioners. In addition, any interested party is provided an opportunity to speak.
- (5) Following the hearing, the three commissioners meet, make their proposed decision, and instruct their staff to prepare the panel report to the full 15-member commission. According to one staff member, several drafts often must be prepared.
- (6) The three-member panel decision then is considered by the full 15-member commission at its next monthly meeting.

Although several panel decisions have engendered considerable discussion in the full commission, few panel decisions have been reversed or modified.

The annual hospital budget reviews do not require site visits. Otherwise, the hearing procedure is identical to that described above.

Division of Health Care Finances

This division reviews the costs, rate schedules, and budget documents of health care facilities. Its duties are varied and it deals with the complex problem of cost determination, a problem over which reasonable

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Possibly Effective: Management of vertigo associated with diseases affecting the vestibular system.

Final classification of the less than effective indications requires further investigation.

CONTRAINDICATIONS. Administration of Antivert (meclizine HCl) during pregnancy or to women who may become pregnant is contraindicated in view of the teratogenic effect of the drug in rats.

The administration of meclizine to pregnant rats during the 12-15 day of gestation has produced cleft palate in the offspring. Limited studies using doses of over 100 mg./kg./day in rabbits and 10 mg./kg./day in pigs and monkeys did not show cleft palate. Congeners of meclizine have caused cleft palate in species other than the rat.

Meclizine HCl is contraindicated in individuals who have shown a previous hypersensitivity to it.

WARNINGS. Since drowsiness may, on occasion, occur with use of this drug, patients should be warned of this possibility and cautioned against driving a car or operating dangerous machinery.

Usage in Children: Clinical studies establishing safety and effectiveness in children have not been done; therefore, usage is not recommended in the pediatric age group.

Usage in Pregnancy: See "Contraindications."

ADVERSE REACTIONS. Drowsiness, dry mouth and, on rare occasions, blurred vision have been reported.

More detailed professional information available on request.

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men can disagree as evidenced by the variations in Medicare, Medicaid, Blue Cross, and private insurance carriers' reimbursement rates. The primary problem in establishing actual costs results from disagreements over how to allocate indirect costs, especially bad debts, teaching costs, and a variety of overhead expenses. Add to this considerations of whether these hospital costs should be calculated on a retrospective basis or on a prospective (i.e., projected) basis and one begins to gain some insight into the complexity of cost determination, rate setting, and revenue estimation.

Budget Review. Annual budget reviews are a fundamental component of the commission's work since budget analysis establishes the basis for a hospital's overall revenues during the coming year. Budgetary controls on hospitals in Connecticut exist because the commission attempts to control the bottom line—total revenues and total expenditures. The commission has not established a schedule of prices for particular services or for particular surgical operations. It must be emphasized that all commission decisions are based on estimated revenues and estimated costs, not audited figures.³

By law, every hospital and any other health care facility or institution requested to do so by the commission is required to submit its operating budget for the coming fiscal year. Budgets must be submitted at least 90 days prior to the proposed adoption date, and the commission must approve, modify, or deny budgets within this same 90 day period. Because of manpower limitations, only budgets from Connecticut's 35 acute care hospitals have been scrutinized, although budgets of long-term facilities may be analyzed within the next two years.

In fiscal year 1974-75, the commission limited its detailed review of budgets only to those facilities whose estimated revenues were projected to increase by more than eight percent over the previous year's revenues. More than one-third (13) of the hospitals requested revenue increases of less than 8 percent and were not required to submit their budgets to public hearings.

In fiscal year 1975-76, all hospitals' budgets were subjected to a preliminary review in which expenditures and revenues were measured against past years' figures and against figures from hospitals with similar services. Cost screen indices were developed to ascertain the propriety of expenditure and revenue requests: a 7 percent salary increase limit and 12 percent nonsalary increase limit were approved. Public hearings were held for all 35 proposed hospital budgets as no hospital budgets satisfied the cost screen criteria.

Rate Review. Requirements regarding rate increase requests are written into the law:

- (1) Any acute care hospital proposing an increase in daily room rates and/or aggregate special services charges in excess of 6 percent over a 12-month period or 10 percent over a 24-month period must seek commission approval and submit to a public hearing. For long-term care facilities the appropriate limits are 4 percent over a 12-month period or 6 percent over a 24-month period.
- (2) Any health care facility proposing an increase in daily room rates or aggregate special services of at least 2 percent but less than the minimum amount for that class of facility must inform the commission of its intent, but unless this increase is deemed unreasonable, the rate becomes effective as proposed. For all types of rate requests, the commission must be notified at least 60 days prior to the proposed implementation date.

Division of Health Care Planning

Pursuant to Section 16 of the law, capital expense budgets of all 35 general or acute care hospitals in Connecticut must be submitted annually to the commission for approval. All capital expenditure proposals over \$25,000 must receive commission approval. Proposals for capital expenses between \$25,000 and \$100,000 generally are handled by staff reports and subsequent recommendations to the full 15-member commission at its periodic meetings. Proposals exceeding \$100,000 are submitted to hearing panels composed of three commissioners and are channeled through the hearing process previously described.

In addition to approval of capital budgets, the commission must approve all new services and equipment costs exceeding \$25,000. Staff in the Division of Health Planning also review capital expenditures for nursing homes, rest homes, homes for the aged, issue certificates of need, and review long-term care project proposals for possible time extensions of their building authorizations.

All of these activities are intended to reduce medical care costs in the State but documented cost reductions will capture only a portion of the total savings to Connecticut's residents. For instance, staff members assist health providers in the development of needed programs and in the alteration and modification of preliminary proposals. The amount of financial benefits from the staff's technical assistance activities has not been determined by the commission.

Nor has the commission estimated the potential long-term financial savings resulting from recommendations of task forces on primary care, long-term care,

hemodialysis centers, cardiovascular surgery, and acute care facilities. Through planning, these task forces are attempting to avoid duplication of facilities and unnecessary services and thereby aid future cost containment efforts.

Future Directions in Cost Containment

While the regulatory activities described above appear extensive, officials indicate that only a fraction of their existing regulatory authority has been implemented. For example, in all likelihood, nursing homes soon will be required to submit their budgets for review and approval.

In Connecticut, the commission's regulatory activities may expand considerably during the next two years. The commission has plans to (1) equalize rates paid by third party payors; (2) permit Blue Cross and commercial insurance representatives to participate in commission hearing panel activities; and (3) add significant auditing and data processing capacity by contracting with Blue Cross of Connecticut.

Other possible future directions include establishing commission policies pertaining to: (1) unrestricted giving and annual fund-raising money (currently not included in hospital revenues); (2) stipulating maximum allowable cost increases due to capital expansion at the time of commission approval for facilities expansion; (3) an adjustment procedure for rectifying any major differences between approved budget expenditures and revenue estimates and actual expenditures and revenues; and (4) changing the method of awarding nursing home bed allotments from a first-come basis to competition based on past performance among nursing homes in a given region of the State.

Reviews of physician costs (pathologists, radiologists, and anesthesiologists) in hospital budgets, a detailed schedule of prices, and state audits of hospitals also have been suggested to the commission.

Legislation has been proposed that would change the reactive nature of commission decision-making. Currently, no action regarding nursing home rates can be taken by the commission unless the home has filed a rate increase application. The legislation introduced would allow the commission to commence rate proceedings in the absence of applications for rate increases.

An Overview

The primary benefits of regulation, according to commission staff members and representatives of third party payors, include:

- (1) Better cost containment in the short time-frame (1-3 years);

- (2) Laying the groundwork through task forces and special planning studies for long-term cost containment by avoiding unnecessary facilities and duplication of services;
- (3) Building a capacity through experience by state officials to develop criteria for determining needs in the health field;
- (4) Encouraging business-like practices in hospital management;⁴
- (5) Creating a public dialogue and awareness of hospital costs, budgets, and programs;
- (6) Reducing the number of unwise and unrefined proposals for capital expansion by providing technical and planning assistance;
- (7) Serving as a catalyst for statewide planning (HSA's PSRO); and
- (8) Acting as watchdog on hospital activities and having the psychological effect of being a review agency.

One demonstrable positive benefit attributed to the commission's presence has been establishment of an eight-hospital consortium in the central Connecticut region. Agenda topics have included collective purchasing agreements as well as the possibility of joint medical staffs among consortium hospitals.

One unanticipated consequence has resulted from the hospital rate negotiating process in Connecticut. Hospitals in the State have their budget expenditures approved by the commission but also must meet with Blue Cross to establish acceptable reimbursement rates. Whenever the commission or Blue Cross approves a higher level of expenditures than the other party deems reasonable, hospital administrators have an added bargaining tool in their negotiation with the other party, be it Blue Cross or the commission. Equalized third party payments should correct this problem as well as save time by eliminating the existing duplication of cost negotiation efforts.

Patterns of medical care in Connecticut have not been appreciably altered by regulatory activity although hospitals have increased patient volume to increase revenues. While fears had been expressed prior to establishment of the commission that quality of medical services would suffer from unwise cost containment regulation, no one asserted this change had occurred. To date, there is no indication that regulation has engendered productivity increases. Nor has any pattern been revealed indicating that certain hospital services are likely candidates for economizing. One hospital administrator noted, however, that hospitals are changing their services mix since activities must pay their own way. For example, services in outpatient clinics for the indigent may be reduced or

terminated entirely, and in other instances purchases of very specialized equipment may be postponed.

There are criticisms, however. A frequent criticism from hospital administrators is that they spend additional time attending training sessions on budgetary procedures, compiling budget information, and preparing their presentations to the hearing panels.

While hospital administrators are not unanimous in their appraisal of the commission, the Connecticut Hospital Association is not working for dissolution or major restructuring of the commission. Nor is the physicians' association, the Connecticut Medical Society, adamantly opposed to the commission. According to a representative of the medical society, the commission's activities have had inconsequential effect on most physicians. Many physicians in Connecticut do not even know the commission exists.

No state official indicated health care regulatory activities will be discontinued. In fact, all indications point to an increased scope of regulatory activities. Political support for deregulation seems minimal. Expansion of regulatory activities and attempts to further reduce annual price increases no doubt will encounter great opposition. For instance, a hospital association spokesman suggested that to date the commission has only controlled charges and not hospital costs, thus something would have to give before long.

Specific Accomplishments⁵

In a draft report of its 1975 activities, the commission reports the following results:

- (1) Forty applications for capital expenditures over \$25,000 were received from health care facilities. The requests totaled \$63,000,000 and the commission denied approval for approximately \$12,000,000.
- (2) Connecticut's 35 hospitals, in their annual capital budget proposals, requested approval of more than \$25,000,000 worth of facilities. The commission denied approximately \$6,000,000.
- (3) Twenty-nine certificate of need requests for long-term care capital projects exceeded \$51,000,000. Nearly \$13,000,000 worth of these projects were denied by the commission or were withdrawn from consideration during the hearing process.
- (4) One hundred and twenty-nine nursing homes, rest homes with nursing supervision, and homes for the aged applied for rate increases totaling nearly \$15,000,000. Nearly \$2,000,000 of these rate requests were rejected by the commission.
- (5) The 35 hospitals proposed an aggregate increase in their total revenues of more than

\$93,000,000. Of this amount, \$66,000,000 was requested for price increases and \$27,000,000 in additional revenue was projected to occur from changes in volume. Of the total revenue requested, over \$84,000,000—90 percent of the total request—was approved. The commission approved \$60,000,000 of the \$66,000,000 in estimated revenues due to price increases. Less than \$3,000,000 of the \$27,000,000 in proposed revenue increases (due to increased volume) was denied.⁶ The average price increase granted was 9.6 percent while the range was 4.8 percent to 18.5 percent. With a different measure for fiscal year 1974, percentage of increase in cost per adjusted patient day, the commission reported an 8.4 percent increase whereas the commission reported that the nationwide figure was 10.9 percent.⁷

Regulation of health care costs by the Connecticut commission probably has saved money for patients and insurance companies. The commission was praised by the Health Insurance Association of America in its December 1975 issue of *Viewpoint*. The association concludes that the CHHC has brought the citizens of Connecticut "significant health cost savings." However, quantitatively assessing health care regulation is not an easy matter. Merging patient equity, providers' needs, and quality of care is a complex task. Highly qualified health economists will differ on the reasonableness of rate decisions and controls.

REFERENCES

1. In a memo dated July 15, to the Commissioner of Health, the deputy director of the finance division stated the following professional manpower needs: cost analysis nursing homes—7; cost analysis hospitals—6; budget analysis—5; rate review and hearing—4; field audit—6; management audit—3.
2. This material has been condensed from the "First Annual Report to the Governor and General Assembly," Commission on Hospitals and Health Care, dated January 1, 1975, pages 9-10.
3. While prospective rate setting offers many advantages, the problems of utilization forecasting and intentional underestimates of revenues remain. At this time, the commission has no policy for adjusting estimated revenues after audited figures become available. However, under section 19-73q of the Connecticut General Statutes, the commission may request the courts to enforce compliance with any commission order or authorization.
4. A state legislator in Connecticut declared that hospitals have never had a cost control emphasis because hospitals always were competing in prestige, not in price.
5. Equivalent information for 1974 may be obtained from the 1974 annual report of the commission.
6. Note that these decisions were made with estimated revenues and estimated expenditures. Hospitals may request rate increases due to unanticipated conditions, and in fiscal year 1975, five acute care hospitals were granted additional rate increases.
7. See the *Second Annual Report to the Governor and General Assembly*, Connecticut Commission on Hospitals and Health Care, January 1, 1976, page 1.

Month in Washington

Washington lawyer, Joseph Califano, Jr., one of Lyndon Johnson's top "Great Society" architects, has been named Secretary of the Health, Education and Welfare Department.

The 45-year-old native of Brooklyn is regarded as one of the Capitol's brightest men. He knows the workings of government inside out. He knows most of the Congressmen of importance to HEW. And he knows most of the programs—many of them established during the "Great Society" days—that he will now administer.

The appointment of Califano to the politically sensitive position was the final cabinet selection by Carter, and was one of the best received. Liberals, including Ralph Nader, saw in Califano's "Great Society" background a promise of a bigger and better "Great Society"; conservatives found reassurance in Califano's reputation as a steady political veteran who is interested in cutting down on waste and inefficiency.

Most of Califano's efforts on behalf of Johnson as the President's chief domestic adviser in the mid 1960's was in the welfare and education areas rather than health where he doesn't have much of a track record.

He knows what he is up against at HEW. In a speech last summer, Califano said a new President will have a tough time coping with the entrenched bureaucracy. "The departments and agencies of the federal executive are a minefield of bureaucratic interests jealous of their jurisdictional turf," he said. The programs and their constituencies outside government "will be poised to oppose any change in the status quo."

Califano carved a reputation as an exceptionally able lawyer during the out-in-the-cold eight years of Republican administration. It isn't unusual for top officials of outgoing administrations to land plushy jobs with Washington law firms, but Califano demonstrated that he was far more than a contact man. He was with the famous Arnold and Porter firm here, then he teamed with the equally prestigious Williams (Edward Bennett) and Connolly firm where he served as counsel to the Democratic Party for two and a half years. After Harvard Law School he joined a New York law firm which once was headed by Thomas E. Dewey.

Califano was first attracted to Washington with the election of John Kennedy. He joined the Defense Department where he quickly became one of Defense

Secretary Robert McNamara's "Whiz Kids". Lyndon Johnson asked him to come to the White House to serve as his domestic aide. There he was known as a driving, tough negotiator between labor and management over wage-price guidelines. He was interested in a systems-analysis approach to budgeting federal agencies which should mesh with Carter's enthusiasm for "zero-based" budgeting.

If Carter carries out his promise to give his department heads plenty of rein in policy matters, Califano might emerge as the chief policy architect in health affairs. Certainly Carter will rely heavily on him for advice. After years as a behind-the-scenes power, Califano will now be in the limelight.

A concerted and united effort by industry and labor to control medical costs is needed to avert a federal takeover of health which would "result in national expenditures of truly astronomical proportions," contends the President's Council on Wage and Price Stability.

Asserting that the day is coming fast when the people discover "how much they must increasingly sacrifice simply in order to maintain the status quo in health care services," the Council said the public's response would be to turn to the government for a solution.

"Absent any major changes in the structure of the medical care system between now and then, the federal government will step in, and when that happens, we are going to be faced with a permanent problem which will defy solution," said William Lilley, acting Council Director, and his deputy James Hedlund.

In a lengthy report on rising health care costs, the Council said "cost control incentives proposed by the private sector—that is, by industry and labor—promise to be more effective than those imposed by the multitude of government agencies which have attempted to tackle the problem . . . the private sector is motivated by an economic incentive which the government will simply never share."

The report said the government, in its Medicare and Medicaid programs has a poor record of controlling costs. "The blizzard of rules and regulations which would accompany full federal financing and administration of the health industry would add to costs and reduce the limited incentives that now exist for efficiency and cost containment," the Council said.

The report pointed to company programs which encourage a second opinion before elective surgery.

Some corporations have set up inhouse medical facilities because they have learned that this is a less expensive way of providing their employees with health care, says the Council. "Health maintenance units with salaried physicians have reduced costs, according to the report. In other localities, corporations and unions have become involved on hospital boards and areawide planning bodies to eliminate duplication of facilities and introduce other cost-saving efficiencies."

The Council said "the private sector must step up its efforts many fold—it must apply the full measure of ingenuity and management skills which are so characteristic of the American system. In short, the private sector must start doing more, a lot more."

The report mentioned "strong opposition from a highly respected, well-organized medical establishment. Private efforts at cost-control are difficult to undertake in the face of this opposition, and difficult to achieve, but we remain convinced that the goal of quality health care, at reasonable costs, is attainable within the context of a largely privately disciplined system. Indeed, we feel it is only within the context of the private system that it is attainable."

The American Medical Association and state and local medical associations "have played a central role" in helping the Senate spotlight Medicaid fraud and abuse. The credit was given by Sen. Frank Moss (D-Utah), Chairman of the Senate Aging Subcommittee that conducted the well-publicized investigations of "Medicaid Mills" earlier this year.

The Senator also said "the number of physicians who cheat" is very small.

In a letter to Richard E. Palmer, M.D., President of the AMA, Moss said "The Illinois Medical Society, the Chicago Medical Society and the Illinois Physicians' Union were directly responsible for my subcommittee's exposure to the problem of Medicaid 'Mills'."

The abuses highlighted in the subcommittee's report "exist for many reasons but AMA inaction isn't one of them," said Moss.

The Senator said the subcommittee's criticism "was not directed at contemporary medical practice."

"It was directed at a growing aberration in our urban ghettos called the Medicaid 'Mill'. The culprits we identified are greedy businessmen and real estate speculators. The same people we found pyramiding nursing home mortgages in New York. Now they have found a new gray train. They hire foreign-trained physicians (we include podiatrists and chiropractors in the definition) and pressure them to see more and more patients in less and less time. The entrepreneurs keep from 50 to 70 percent of the mon-

ey Medicaid pays to the foreign practitioner"

Poor quality care results, Moss said. "It could hardly be otherwise given the low Medicaid rates, the great delays in payments, the often and arbitrary denials of payment as well as the all-encompassing pressure exerted on mill practitioners to grind patients through the mill. Little wonder reputable physicians avoid Medicaid practice. Even the best intentioned physician would have difficulty functioning in this kind of environment."

In Medicaid, the "ripoffs" are taken by the clinic owners who more often than not are not physicians, said Moss.

The number of providers who abuse the Medicaid system may be four percent of total Medicaid participating physicians (including chiropractors and podiatrists) or less than two percent of all physicians in the United States, he said. This is hardly a blanket indictment.

Moss endorsed a statement by Dr. Palmer that other providers have a far worse track record as far as cheating the system. "I would include, for example, nursing homes, pharmacies that specialize in welfare clientele and clinical laboratories that do a high volume of Medicaid business."

The lawmaker wrote that "only with the assistance of the Medical profession can we seek to end the fraud and abuse which now haunts our government health care programs. We can bring providers who bill for services not rendered to the bar of justice but a more complicated scheme inevitably involves questions of medical judgment which only physicians are capable of rendering."

A commission to study prescription drug usage and adverse reactions has been formed with the blessings of Senator Edward Kennedy (D-Mass.) and the funding of the Pharmaceutical Manufacturers Association (PMA).

PMA answered a challenge by Kennedy that the drug makers confront the problem by agreeing to fund an independent study commission for three years at \$250,000 annually.

"The problem of adverse drug reactions is definitely a problem," stressed PMA's Chairman Robert R. Clark.

Both Clark and Kennedy hope the commission will be able to design a system for post-marketing surveillance of drugs by the Food and Drug Administration so that both adverse reactions as well as new drug indications become more quickly known. Such a system, termed "Phase IV" by Kennedy, could shorten the wait for pre-market approval of new drugs.

Reflections from the Dean's Office

Robert U. Massey, M.D.

Ask a professor of surgery, hospital administrator, or university president to define the university hospital or to describe its goals and you are in for an evening of it. The talk may range from Newman's "The Idea of a University" to Codman's "The Product of a Hospital."¹ More likely neither of them will be mentioned, but rather the difficulties in setting priorities, the tensions between education and service, the costs of medical care, and the economic and ethical problems created by advancing technology may obscure any agreement on purposes or goals. The matter of ultimate purpose will be confused with why and for whom the hospital was built in the first place. Almost everyone will forget about Aristotle's four causes, and that the final cause is different from any of the preceding three.

One university has declared that its hospitals are "for the purpose of teaching allopathic medicine, nursing, and the allied healing arts . . . , and for conducting research in said fields, and incidental thereto, and insofar as the same may be practical, to provide medical assistance to the residents of the State . . ."²; another declared that it was to be an "institution absolutely essential to a medical school, and one which would afford relief and comfort to thousands of the sick and miserable."³ Others have described teaching hospitals as "leaders of progress in medical knowledge in the study of diseases."⁴ Teaching, research, and patient care—the familiar triad appears over and over as the triangular model which each of us can turn so that the suitable apex is in position to support any contention.

Whether the hospital has been designed for faculty members, students, house officers, clinical investigators, or the hospital administrator, its final cause is patient care. Aristotle defined *final cause* as "that for the sake of which something is." It might be argued that health is the final cause, and there is some confusion between health and medical care. The final cause for seeking care is health, but the hospital exists ultimately to care for the sick.

All other functions and products of the hospital are derivative from that. The university will insist that the university hospital was built to provide for teaching in the health professions, and for research, and that it is the classroom and laboratory for its clinical faculty and students. That position is tenable, but those ends are best served only when they derive from patient care as an expression of the hospital's ultimate concern.

More and more of our hospitals are becoming teaching hospitals with university connections. In 1975, there were 103 university-owned hospitals, and an additional 1290 with some form of medical school affiliation.⁵ The number of medical students entering medical school has doubled since 1960, and there will soon be 30,000 students in clinical clerkships. Since 1970 increasing numbers of schools have assumed responsibility for graduate medical education. Affiliations have tripled and the goals of medical schools have become intertwined with the goals of teaching hospitals.

Those goals are not identical; accordingly, faculties and hospital boards, deans and hospital administrators have devised innumerable organizational devices to protect the differences while preserving the interdependence. There are hospital medical colleges in England and university medical colleges without hospitals; there are university hospitals that were built before and after their medical schools. There are separate boards, common boards, and interlocking boards. There are separate budgets and common budgets; faculty members paid by hospitals in whole or in part, and staff members paid by medical schools. Hospitals support research and research supports hospitals.

Each arrangement is a compromise, an expression of a point of view; the care of the sick is not the same as the education of physicians, and may in fact conflict with it. Education may improve care, but sometimes gets in the way. The costs get mixed and should be kept separate; that is not easy.

Whatever the compromise and whatever assumptions are made about costs, the university hospital board and administrator must be unwavering in the defense of their ultimate concern, the *final cause* of the hospital: the best possible care of the patient. Clinical leadership, teaching, and research follow easily; it is difficult to make it work the other way round.

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ROBERT U. MASSEY, M.D., Dean and Professor of Medicine, University of Connecticut School of Medicine, Farmington.

The President's Page



CME (Continuing Medical Education). What is it? Who needs it? How shall it be offered? What are the results? It would seem that the answers should be simple and straight forward. In truth, however, there is much controversy and indecision. I do know that my own ideas on the subject have changed markedly. In considering the matter, I would suggest that there is all too much attention being paid to form rather than substance. There is only one purpose involved and that is to provide for the very best in patient care. There are three main areas to be considered in discussing CME, namely (1) availability; (2) utilization, and (3) results.

There can be little argument but that we have sufficient knowledge available to us and that there are enough ways for us to obtain this knowledge. However, it must be emphasized that we need not all obtain our education through the same channels. Some prefer to concentrate on medical journals. Others prefer didactic courses. Still others prefer seminars and other informal discussion groups. There can be various combinations of the above as well as other routes. We have reached a stage in our professional development, however, where we should make our own selection, where we must decide for ourselves the best way to keep up with constantly increasing medical knowledge.

Having decided for ourselves how we are to obtain information, there must then be some mechanism to evaluate how we have utilized it. Again the question arises as to how this is best done. The arguments here are not new. Certification by means of testing occupies a time-honored place in our scheme of evaluation. For as long as it has prevailed, however, there have been the arguments that one's ability to prepare for a test does not necessarily correlate with one's ability to practice sound medicine and use good clinical judgment. On the other hand, if one can demonstrate sufficient knowledge to pass a test, at least it demonstrates that the information has been mastered for this one occasion. What we need then is the opportunity to satisfy ourselves that we are keeping up with the advances being made. We do not need mandated attendance at formal sessions. We do not need to obtain a specific mark in a test. We do need a way, however, to evaluate our efforts and it seems to me that the present trend toward self-assessment testing should meet this requirement.

Finally, the value of the educational process must be determined by the results obtained. Our goal is patient care and the ultimate reason for the entire educational process is to provide for the best in this respect. We have developed monitoring mechanisms to determine the quality of patient care. This task must be undertaken with sincerity. Instances which demonstrate a lack of sufficient information on the part of the physician must be sought out and followed up by assurance that education is obtained to correct this deficiency. This is the goal of all of our review procedures, but only in this way can continuing medical education serve a worthwhile purpose.

The purpose of CME is not to fulfill meaningless requirements but rather to obtain information that will enable us to provide better care for our patients. We need a way to evaluate for ourselves how well we are doing and beyond that need impartial peer review to be sure that the information obtained is put to good use.

Hilliard Spitz, M.D.
President

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EDITORIALS

The Unborn Child

Prenatal human life has assumed notable prominence among the concerns of physicians, scientists, and medical ethicists. In 1971, John Fletcher, an ethicist with special interests in genetics and reproduction, suggested that prenatal life was emerging as a new stage in the human consciousness.¹ He attributed this phenomenon to modern progress in understanding fetal life and to our recent ability to safely invade the fetal environment. As a consequence of this new consciousness, we are defining and redefining our views about the unborn human being and will likely continue the process for a decade or more.

During the past several years there has been considerable increase in fetal research. Some of the experimentation came under strong criticism as transgressing accepted standards of medical ethics. This criticism, combined with the efforts of persons who were fighting increasingly permissive abortion practices, led to congressional legislation in 1974. The legislation temporarily halted certain kinds of fetal research and established an investigative body to recommend regulation of future research. In the spring of 1975, the Connecticut State Legislature considered legislation (proposed bill 8419) which would have prohibited nonbeneficial research with fetuses and with children. That legislation was not enacted, largely because of the intensive ongoing regulatory effort which was soon to lead to new regulations at the federal level.

The National Research Act of 1974 (Pub. L. 93-348) established a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission was given the

responsibility for studying and making recommendations about all human research, but especially about research with human beings who had restricted capacity to understand or consent. First among the areas studied was research on the fetus. Subsequent areas have included children, prisoners, and the mentally disabled.

As part of its investigation of fetal research, the Commission asked for a review of the scientific literature and for the views of several ethicists and legal scholars. Six colleagues and myself carried out the literature review. We documented an extensive amount of fetal research which met accepted ethical standards for medical research in this country and elsewhere; we also found a handful of experiments suggesting abuse of those standards.

In addition to providing a summary of published fetal research, we also submitted, at the Commission's request, our own ethical views on the subject. The views were the composite from seven persons: a biologist and legal scholar; a bioethicist; and five physicians who were actively engaged in fetal research or pediatric research. This part of our report to the Commission is published elsewhere in this volume.

A major premise of our ethical analysis and of the Commission's approach to the fetal research issue was the basic acceptance of the fetus as a human subject who was fragile and vulnerable, and who deserved care and respect. When one considers categories of research which may be permissible with vulnerable individuals, the most difficult questions arise about nonbeneficial research. Can it be condoned at all, and, if so, under what circumstances?

Nonbeneficial research, often termed nontherapeutic research, is research which is not designed for the direct benefit of the individual research subject. Instead its purpose is the benefit of a class of individuals who often are not even available

until some later time. The expansion of knowledge about normal individuals is a common justification for nonbeneficial research, since the knowledge will form the base from which deviancy from normal is understood and future therapies are designed. But can this justification extend to using a research subject who cannot understand the research, or consent to her or his participation, especially if some risk exists for the subject? The unborn child, as a participant in nonbeneficial research, is often in this position.

Investigators recognize that essentially all research carries some small risk for the subject. They equally recognize that understanding and progress in solving health problems are slowed or halted if questions cannot be answered by controlled data collection, including data about normal individuals. When the question is posed of how to justify participation of unborn children in research which will not directly benefit them (the question is identical for children after birth), the other side of the coin asks how we could justify not addressing the many health problems of this group in a careful, intelligent manner.

The National Commission accepted the premise that research with human fetuses was necessary for controlling fetal disease and understanding human biology. The task thus became the construction of adequate safeguards for the vulnerable fetal subject. The recommendations that were generated for the conduct of fetal research included the following: Research, whether beneficial or nonbeneficial, should only be undertaken when important knowledge was expected which was unobtainable by other reasonable means. Proposed research had to be preceded by studies with animals and nonpregnant persons when possible. If nonbeneficial research were being considered, only studies that carried no risk or minimal risk for the fetus would be appropriate. The Commission also insisted that any research with pregnant or potentially pregnant women be initiated only after thorough consideration of risks to the fetus and a decision that they were acceptable.

The Commission worked hard to keep separate the issues of fetal research and abortion. Fetal research in a setting in which abortion was being contemplated or had been elected would be permissible only if that same type of research was deemed permissible in pregnancies which would continue to full term. This meant that only one class of fetuses was to be considered with regard to research questions and the presumption that certain fetuses would die by abortion was irrelevant to the question of risks to the fetus.

The Commission forwarded its report and recommendations to the Secretary of the Department

of Health, Education, and Welfare in May, 1975, and the Secretary issued regulations based on those recommendations in August, 1975.² The regulations govern research activities, i.e. the planned collection of data according to a protocol, as opposed to innovative therapy initiated by an individual practitioner caring for a patient. Protocols are carefully reviewed by local institutional review boards, as well as by HEW, with the main purpose being the protection of human subjects, in this case, the protection of unborn children. These review boards have lay participation in addition to medical and scientific expertise.

In Connecticut, research with pregnant women or with fetuses is reviewed at one of our two schools of medicine. Research supported by sources other than HEW and initiated outside of Yale University or the University of Connecticut could escape review, although, to my knowledge, no such research has occurred in the state in recent years. Action by the federal government is expected to extend the requirement for ethical review to all human research. This requirement should be encouraged so as to provide thorough and uniform protection for all human subjects, born and unborn, who participate in the quest for better health and a better life.

Maurice J. Mahoney, M.D.

*Associate Professor of Human Genetics and Pediatrics
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For a Federal Immunization Insurance Corporation

Our vaccination program for children may be endangered because of mounting liability problems. Connecticut, like most states, has legal requirements for immunizations before admission to elementary school, and since school attendance is also a requirement, some immunizations become in fact mandatory.

It is impractical, particularly in mass immunization programs, to warn sufficiently about the odds of serious complications, for example, of paralysis after polio immunizations or CNS damage from the pertussis vaccine.

Since serious adverse effects are rare and few compared to the benefits, physicians strongly recommend immunizations. It is unreasonable and unfair to burden parents fully with the responsibility of decisions for or against immunizations, based on descriptions of benefits and hazards.

From observing 10,000 people signing consent forms before flu immunizations, it appears that less than 3 percent read the forms and fewer understand it. This is a cumbersome time consuming and useless ritual. In regards to children, whether or not such proposed forms are read and understood by parents, the procedure of more forms would further interfere with attempts to reach high levels of immunizations in communities. Since physicians often have a difficult task persuading the public to have their children immunized even without providing information about major hazards, the following measures would help greatly the interests of public health:

1) If immunizations are recommended in the interest of the individual *and* to protect the community against communicable diseases, those suffering permanent damage as a consequence should receive compensation from public funds. The financial burden should be carried by a governmental source rather than by the vaccine manufacturer or the physician, provided that no negligence on their part is involved.

2) Lack of "informed" consent or of "full" information before immunizations should not be considered negligence on the part of the provider since the delivery of such detailed information is impractical if not impossible, particularly in mass immunization campaigns.

3) Schedules for reasonable compensation should be established on a national level for those suffering permanent damage from the administration of mandatory or of recommended immunizations and the required funds should be available through a specially established Federal Immunization Insurance Fund.

4) Any sums allocated for sustained permanent damages from such immunizations should be in the nature of monthly payments rather than lump sum assignments, to reduce the possibility of misuse.

5) Under this program, if attorneys are representing a claimant such attorneys should be compensated according to predetermined and fair fee schedules. It should be made unlawful that they share in the compensation provided for those who sustained damage unless negligence is involved.

The case *for* immunizations against polio, measles, diphtheria, whooping cough, and other such preventable infections is beyond debate. The question of compensation in case of permanent adverse effects should be settled forthwith before the entire vaccination system flounders. Neither the medical practitioner

nor the manufacturer should be liable for a procedure that authorities promote in the public interest.

Hans H. Neumann, M.D.
Medical Director

*New Haven Health Department
New Haven, CT.*

The Journal Budget—1977

Connecticut Medicine has joined those publications hurt by inflation. The House of Delegates, at its December meeting, voted to accept by a narrow margin the recommendation of the Council that the 1977 Journal budget be maintained at its 1976 level, thereby necessitating that the average issue of the Journal be cut from its present 80 pages to 72. The causes for increased costs are obvious: in paper, printing, labor, postage, etc.

The details of the process by which this decision was made are important to an editor, and though probably not for the average member, I should briefly explain it. It began during a Publications Subcommittee meeting of the Council called to examine in detail the 1976 Journal budget and its expenses. A question, not on the agenda, was asked of me: "What would I do if the 1977 Journal budget were cut \$20,000?"

At the next step in the process about a week later, I gave an answer to this question to the Finance Subcommittee of the Council. A \$20,000 cut would necessitate decreasing the present 80 pages of an average issue to about 56, obviously an emasculation of the Journal if adopted. The committee, however, recommended to the Council that the 1977 Journal budget be maintained at the 1976 level, in effect cutting the 80 pages per issue to 72 because of inflation.

Next, to the Council. Though it commended the improving quality of the Journal, it noted that to maintain it at the present 80 pages, a dues increase of about \$2 per member would be necessary, and about \$1 per member for 76 pages. It defeated a motion to raise the dues sufficiently to maintain the present number of pages, and then approved the recommendation of the Finance Subcommittee—that dues for the coming year be maintained at the 1976 level. The House of Delegates essentially duplicated the action of the Council—it commended the Journal, but narrowly defeated a motion to increase the dues even a small amount to maintain the present number of pages in the Journal. The dues will remain at the 1976 level of \$100.

The membership can rest assured that the Council keeps a close watch over the budget. There is not a bit of fat in the Journal budget. It is no accident that our dues of \$100 tie with Missouri's as the lowest of any state society in the country.

During the process from committee to committee, I was asked if the cut would lower the quality of the Journal. In spite of our efforts, I think it will. I was also asked what size Journal would I opt for if money were of no consideration. I replied 88, for this reason: During this past year, the Journal has developed a momentum of its own so that I have material educational and informative to the membership, enough to fill such an issue and to improve it.

Though disappointed, I of course realize that it is the Council and the House of Delegates that establish our priorities and set limits to our budget. As for the Journal, in the final analysis it is the members, especially by letters to the Editor, critical as well as commendatory, that tend to establish the consensus that influences the Council and our delegates. And this is what I hope for in the coming year—continual written expressions of opinion to the Editor from the members—good or bad.

Fred Fabro, M.D.

a 8 day period. There were no pneumonias, no fatalities. Six of these patients had pharyngeal cultures and acute and convalescent serum titre performed by the State Department of Health Virology Laboratories.

Findings were all negative for organisms as itemized in Table I.

Table I

Cultures: Respiratory Group, Influenza type A and B, Para influenza 1, 2 and 3 (a sub-group of para myxo viruses), Adenovirus group, Respiratory syncytial group, Encephalitides group, Mumps, Herpes simplex.

Serum titre: All the above plus Psittacosis, Q fever and Primary atypical pneumonia (Eaton agent or Mycoplasma pneumoniae).

Following this outbreak there were no other upper respiratory infections reported through our surveillance mechanism. The possibility that a clinical toxin was involved in this outbreak seems very remote.

Comparison of this outbreak to the Philadelphia outbreak is difficult to make since at this point only newspaper reports are available to most physicians. However, in a very miniaturized form, there appears to be a similarity in that no organism could be identified and the outbreak was self limited without a secondary wave of infection.

The speculation offered is that such outbreaks may occur often, but unless of a serious or fatal nature, go unnoticed and unreported. The speculation is that there may well be many viruses or other infectious agents of an upper respiratory nature that our laboratories are as yet unable to identify. Further, that these agents, lethal and nonlethal, for some unknown reason appear in outbreak epidemic form and, again for no apparent reason, are quite self limited and spontaneously subside.

Ludmil Chotkowski, M.D.
Chief of Medicine

Connecticut Valley Hospital
Middletown, CT

Letters To The Editor

Letters to the Editor are welcomed and will be published, if found suitable, as space permits. Like other material submitted for publication, they must be typewritten *double spaced* (including references), must not exceed 1½ pages in length and will be subject to editing and possible abridgment.

MINI LEGIONNAIRES DISEASE?

To the Editor: In the early part of October there occurred at the Connecticut Valley Hospital in Middletown a sudden outbreak of upper respiratory disease in a particular unit of the institution which ended just as abruptly as the "Legionnaires' disease" without a secondary wave of infection, and for which no viral or bacterial organism could be isolated, and for which acute and convalescent sera determinations were normal. This observation is being reported since there continues to be great interest for any possible explanation of the outbreak during the Philadelphia American Legion Convention.

On October 2, 1976 four patients in a unit of 29 patients in Connecticut Valley Hospital complained of general malaise, nonproductive cough, temperature and sore throat. The following day three more patients had the same symptoms. A total of 14 patients and 1 nurse experienced these same general symptoms over

MALPRACTICE AND DERMAL FREEZING

To the Editor: In this era of menacing malpractice suits, the following observations appear to be important, and should be reported to the members of our profession.

Dermal freezing for the purpose of topical anesthesia prior to injections, minor incisions or for the relief of minor sport injuries, muscle spasms, etc., has been and is being used widely. The new topical freezing agents, containing Trichloromonofluorethane and Dichlorodifluorethane, have a more intensive freezing effect, and at the same time a more pronounced dermal reaction than the older Chlorethyl spray. But even this spray may produce the same phenomenon if it is being used long enough until a wide snow-layer forms.

In individuals with dark skin, the post refrigeration hyperemia and erythema may lead to hyperpigmentation which may remain permanently in a high percentage of cases, although some fading may occur with passing time. This pigmentshift phenomenon is similar to the sequelae of first and second degree burns as occasionally seen in dark skinned individuals. In one of my patients dark areas could be seen thirteen years after "skin freeze". As a rule I did not find this phenomenon in blond and light-skinned individuals. Only two persons in a series of over 5,000 applications showed slight brownish blemishes four months after "Aerofreeze" use. They were women in their eighties.

A written informed consent, signed by the patient before using the "Freeze Spray" is advisable. All my patients, to whom I pointed out the cosmetic hazards refused the procedure with exception of one lady.

The probable reason why I have not encountered any malpractice suits is the unnoticed location of the hyperpigmentations, the lower back, hidden to the eyes of the patients. Other regions like hands, arms, face, breasts, neck, etc, will probably induce some patients and their lawyers to start malpractice proceedings. Skin freezing prior aspiration of breast or thyroid cysts may be especially hazardous from the cosmetic standpoint.

A book written for laymen titled "Malpractice and You" instructs the public about the mechanics of malpractice suits.¹

Egmont J. Orbach, M.D.

New Britain, CT

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PRESCRIPTIONS AND THE PHARMACISTS

To the Editor: At the last meeting of the Joint Conference Committee of the Connecticut State Medical Society and the Connecticut Pharmaceutical Association, held September 2, 1976, two matters were introduced by Mr. John J. DeNicola Jr. R.Ph., President of CPA which are of great concern to pharmacists.

Mr. DeNicola stated that many prescriptions are appearing in pharmacies which are stolen, some from medical practitioners, others are stolen from hospitals. He stressed the fact that this was a serious problem for pharmacists. The areas of greatest concern were the larger cities, especially New Haven. He hoped the JCC would alert medical practitioners to use greater care with their prescription blanks and not leave them around loosely in their offices. There was also need of greater security in hospitals to prevent loss of prescription blanks.

Mr. DeNicola discussed the problem of multiple prescriptions on one prescription blank. Some physicians are not aware that pharmacists must keep three separate prescription files by law: (1) — All prescriptions written for class 2 substances. (2) — All prescriptions written for class 3, class 4, and class 5. (3) — All prescriptions for non-controlled substances. Multiple prescriptions on one blank can create problems for pharmacists when filing written orders of physicians.

The JCC were in accord with Mr. DeNicola's concern. It is hoped that this letter will alert physicians of the seriousness of these problems and to remind them to use care and caution with their prescription blanks, to avoid loss due to stealing.

(Prescriptions for any controlled substances should include the following information in the hand writing of physicians: (1) Name and address of patient (2) Age (3) Name and address of physician (4) DEA Registry Number (5) Signature.)

Bernard O. Nemoitin, M.D., Chairman
Chester A. Potrepka, R.Ph., Secretary

The Joint Medical-Pharmaceutical Conference Committee

NOTICES

ST. FRANCIS HOSPITAL March 24, 1977

The Immunology Division of the Department of Laboratories is pleased to announce the following lecture as a part of the continuing series of lectures on "The Current Concept and Trend in Clinical Immunology".

LECTURER: Deborah Doniach, M.D., Professor of Clinical Immunology, The Middlesex Medical School, London, England

9:15 a.m.—10:15 a.m.

Medical Grand Round—Autoimmune Markers in Chronic Liver Diseases

11 a.m.—12 noon

Autoimmunity to Human Pancreas and Pituitary

PLACE: Amphitheater, ST. FRANCIS HOSPITAL,
114 Woodland St., Hartford, CT

There will be an informal luncheon reception following the lecture.
FOR RESERVATIONS PLEASE CALL:

Jayson Hyun, M.D.

Director of Immunology Laboratory

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Deadline for applications: April 15, 1977

Applications are now being received for a postdoctoral training program designed to develop skills to engage in professional careers as investigators and teachers in the field of mental health program evaluation and research. The program consists of course work and opportunities for interdisciplinary research and can be structured for a period of two years. Applicants must have a doctoral degree in medicine, epidemiology, public health, nursing, social work, or the behavioral or administrative sciences.

The program is funded by the Alcohol, Drug Abuse, and Mental Health Administration of HEW, and provides for a limited number of stipends between \$10,000 and \$13,200.

The deadline for applications is April 15, 1977. Notification of admission will be made by May 30, 1977. For information write:

Lee D. Brauer, M.D., Program Coordinator
Program in Mental Health Services Evaluation and Research
Center for the Study of Health Services,
Institution for Social and Policy Studies,
Yale University, 77 Prospect St., New Haven, CT 06520

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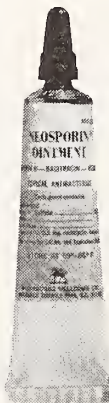
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Prophylactically, the ointment may be used to prevent bacterial contamination in burns, skin grafts, incisions, and other clean lesions. For abrasions, minor cuts and wounds accidentally incurred, its use may prevent the development of infection and permit wound healing. **CONTRAINDICATIONS:** Not for use in the eyes or external ear canal if the eardrum is perforated. This product is contraindicated in those individuals who have shown hypersensitivity to any of the components.

WARNING: Because of the potential hazard of nephrotoxicity and ototoxicity due to



neomycin, care should be exercised when using this product in treating extensive burns, trophic ulceration and other extensive conditions where absorption of neomycin is possible. In burns where more than 20 percent of the body surface is affected, especially if the patient has impaired renal function or is receiving other aminoglycoside antibiotics concurrently, not more than one application a day is recommended. **PRECAUTIONS:** As with other antibacterial preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. Appropriate measures should be taken if this occurs. **ADVERSE REACTIONS:** Neomycin is a not uncommon cutaneous sensitizer. Articles in the current literature indicate an increase in the prevalence of persons allergic to neomycin. Ototoxicity and nephrotoxicity have been reported (see Warning section).

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Assistant Executive Director
Public Affairs

William R. Richards, M.D.
Executive Director
Josephine P. Lindquist
Associate Executive Director

Leonard R. Tomat
Assistant Executive Director
Scientific Activities

CALL ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1977 Annual Meeting of the House of Delegates will be held at the Hartford Hilton Hotel, Hartford, commencing at 8:30 A.M. on Wednesday, April 27.

Hilliard Spitz, President
Timothy F. Nolan, Speaker of the House
Louis C. Backhus, Secretary

INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides:

Resolutions may be introduced by any Active or Life Member of The Society, in compliance with the following provisions.

- a. All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.*
 - b. Component county associations whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc. be considered regular business if they are received later than fifteen days prior to the date of the meeting.*
 - c. Reports, recommendations, resolutions or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered as regular business.*
 - d. Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for consideration by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provision of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.*
-

Summary of Actions Council Meeting

Wednesday, December 15, 1976

Attendance

Present in addition to the Chairman, Dr. D.A. Grendon, and the Vice Chairman, Dr. G.W. Van Syckle, were: Drs. Spitz, Friedberg, Backhus, Nolan, Freedman, Hess, Bradley, Cramer, Fabro, Kamens, James, Mendillo, Krinsky, Sonnen, Whalen, McGarry, Ahrens, Sadowski, Magram, Eslami, Parrella, Barrett, Zlotzky and Middleton.

Also present were: Mrs. Lindquist, Mr. Tomat, Mr. Sweeney and Dr. Richards.

Absent were: Drs. Johnson, Canzonetti, Robinson, Harkins, Beck and Vidone.

Routine Business

Approval of Minutes

It was VOTED to approve the minutes of the combined meetings of October 28 and November 4, 1976,

as published and distributed with the Handbook for the House of Delegates meeting on November 17, 1976.

Life Memberships

It was VOTED to approve applications for Life Membership received from the following eligible Active Members:

Jolan Blass, 173 Hubbard Avenue, Stamford
Justin L. Cashman, 11 St. John Street, North Haven
Gideon DeForest, 309 Edwards Street, New Haven
Milton Fisher, The Putman-weaver Nursing and Convalescent Home, Inc., Weaver Street, Greenwich
Harold J. Greenblatt, 73 Cedar Street, New Britain
T. Stewart Hamilton, Hartford Hospital, Hartford
Neville Kirsch, 61 South Main Street, West Hartford
Ruth W. Lidz, 60 Orchard Road, Woodbridge
Colman Lopatin, 971 Fairfield Avenue, Bridgeport
D. Norman Markley, 422 Farmington Avenue, Hartford

Edward Nichols, 85 Jefferson Street, Hartford
Frank F. Northman, 753 Lakeside Drive, Bridgeport
Renato A. Ricca, 28 Ripley Road, Glastonbury
Jacques Robbins, 5 North Main Street, Enfield
Theodore W. Steege, 85 Jefferson Street, Hartford
Francis W. Trapp, 55 West Main Street, New Britain
Andrew S. Wesoly, 27 Grove Hill, New Britain
Edward P. White, 44 Garden Street, Hartford
Benjamin Wiesel, 85 Jefferson Street, Hartford
Samuel Wolfson, 15 Coolidge Street, New Britain

Election of Student Members

It was VOTED to elect to Student Membership 16 Connecticut residents who are enrolled in medical schools. The names of those elected will be published in an early issue of the Journal.

Date of Next Meeting

The Chairman set the date for the next Council meeting as Thursday, January 20, 1977.

Old, New and Special Business

Progress Report—Connecticut Ambulatory Care Study

It was VOTED to receive as information a communication from Frederick C. Weber, Jr., CACS Principal Investigator, which advised the Council that most of the report on the Study had been completed and been reviewed by the CACS Advisory Committee; that a final chapter of the report was in preparation; and that, following review by the Committee on Statewide Medical Planning, the report would be submitted to the Council for review and evaluation.

Report of Delegate to MSSNY

It was VOTED to receive as information a report filed by Hilliard Spitz, New London, on his attendance at a meeting of the Medical Society of the State of New York (N.Y.C., 11/7-11/76) as delegate from CSMS. It was further VOTED to refer Dr. Spitz' recommendations concerning reference committee hearings as well as other problems besetting recent meetings of the House (shortage of time, etc.) to the Speaker and the Vice Speaker for, in consultation with a member of the Connecticut AMA Delegation, study and report, with recommendations, to the Council.

CHA Presentation re Hospital Budget Cuts Controversy

The Council was joined by Dr. Fred Hyde, CHA Vice President and General Counsel, who made a presentation of the position of the Connecticut Hospital Association concerning the current ongoing controversy between the state's acute care hospitals and

the Commission on Hospitals and Health Care over budgets and budget cuts. In addition to pointing out certain key areas of service that will be affected by the cuts imposed by the Commission, he outlined certain legislative proposals under consideration by CHA which would change the composition of the Commission, spell out the qualifications for Commission members and staff and substitute a number of Health Systems Agency representatives for a similar number of incumbent members now serving as "public" or "consumer" representatives.

Following an extended period of discussion, including question-and-answer exchanges with Dr. Hyde, the Council VOTED to receive the printed materials and Dr. Hyde's presentation as information. It was further VOTED "that the Council express sympathy for the position of the hospitals and the purposes of the Commission on Hospitals and Health Care, and suggest closer constructive cooperation between the Commission and the individual administrators, perhaps with the aid of impartial but experienced consultants. The goal of all parties should be to effect maximum savings in costs and still preserve good quality health care, not by mass, across-the-board regulations, but hospital by hospital". Notice of this expression of opinion by the Council is to be sent to the CHA and to the Commission.

Resignations, Appointments, Etc.

- (a) *Liaison Committee with State Department of Social Services*: It was VOTED to accept the resignation of Robert B. Hurowitz, West Haven, from Committee membership. It was further VOTED to appoint Jeffrey V. Rabuffo, Middletown urologist, to membership on the Committee.
- (b) *Committee on Medical Aspects of Sports*: It was VOTED to appoint Peter Jokl, New Haven, to membership on the Committee.
- (c) *Assistant Executive Director*: It was VOTED to receive written notice from Mr. Leonard R. Tomat, Assistant Executive Director, that he desired to terminate his current employment agreement with the Society within a period of three months. In accepting this notice, the Council expressed regret and thanks for his services.
- (d) *Executive Director*: It was VOTED to receive written notice from William R. Richards, M.D., Executive Director, that he desired to terminate his current employment agreement with the Society not later than December 31, 1977. The notice was accepted with regret.
- (e) *Advisors to American Association of Medical Assistants, Connecticut*: It was VOTED to appoint the following members of the Society as advisors to the AAMA, Ct.: Karl R. Friedmann, Old

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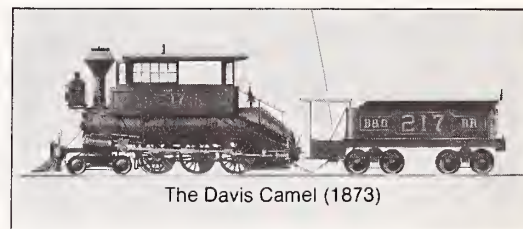
Decongestant action helps control cough and
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Report of Delegates to AMA on Philadelphia Meeting

It was VOTED to receive as information verbal reports on the Philadelphia meeting of the AMA House of Delegates presented by several members of the Connecticut Delegation. Of special interest to the Council was a report that the Connecticut resolution, calling for total AMA funding of all costs (including those of CSMS and NHCMA) of defending against the complaint of the Federal Trade Commission, was *not* adopted. Dr. Cramer indicated that he would submit written material concerning several matters he had reported on verbally. In conjunction with Dr. Cramer's report, it was VOTED to instruct staff to write to AMA to obtain a copy of the document entitled "Criteria for Short-Stay Hospital Review"; and to HEW requesting draft copies of "Monographs" on criteria and standards for project review and planning now under development. It was also VOTED to receive as information a summary of actions taken by the House of Delegates which was published by the California Medical Association.

Dr. Spitz made note of the meeting of representatives of Aetna and of eight state medical societies sponsoring Aetna professional liability insurance programs. In connection with this segment of his verbal report there were received as information, but without vote, the following published documents: A report prepared and submitted by Leonard R. Tomat, CSMS Staff; a proposal offered by Aetna to the meeting participants that described a mechanism by which peer review would be provided when a physician objects to a proposed settlement of a claim by the carrier; a compilation of "facts and figures" which Aetna suggested might be used in a newsletter to the membership for the purpose of providing information on what Aetna and the Committee on Professional Liability are doing to try to resolve some of the problems that have arisen as a result of reclassification.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on December 15, 1976. Detailed minutes of meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*



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In Memoriam

Haines, Robert W., Jefferson Medical College, 1946. Dr. Haines was an ophthalmologist and practiced in New London for eight years and in West Hartford for 27 years. He was on the staff of St. Francis Hospital and St. Mary's Home, both in Hartford. He was a veteran of the Army Air Corps. Dr. Haines was a diplomate of the American Academy of Ophthalmology and Otolaryngology and a member of the Connecticut State Medical Society, New London County Medical Association and Johns Hopkins Medical and Surgical Society. Dr. Haines died September 10, 1976, at the age of 55.

Kornblut, Alfred, New York University, 1920. Dr. Kornblut was a otolaryngologist in the Fairfield area since 1920. He was retired Reserve Captain, serving in World War II. He was a member of the Fairfield County Medical Association, a 50 year member of the Connecticut State Medical Society, and a member of the American Medical Association. Dr. Kornblut died November 15, 1976, at the age of 80.

Palomba, Edward A., Georgetown, 1959. Dr. Palomba was a practicing general practitioner in Somers. He was Chief of staff at Johnson Memorial Hospital from 1969 to 1970, he also was former senior physician at the State Department of Corrections in Somers, Director of the Connecticut Hospital Planning Commission, former Vice President of the Tolland County Medical Society and a member of the Connecticut State Medical Society and the American Medical Association. He was a founding member of the Medical Political Action Committee. He was an assistant medical examiner for Tolland County and physician to the Connecticut Boxing Commission. Dr. Palomba died September 5, 1976, at the age of 43.

Pinn, Abraham S., Syracuse University (pre-med.) and Laval University, 1929. Dr. Pinn was a general practitioner in the New Haven area since 1930. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Pinn died October 12, 1976, at the age of 74.

Prignano, John V., Georgetown University, 1940. Dr. Prignano was a general practitioner in the Hartford area since 1943. In 1947 he was appointed assistant state medical examiner and became a staff member at Manchester Hospital. In 1967 he resigned his medical examiner's post and in 1969 gave up his private practice to take a post as a staff physician at the hospital's

emergency room department, a post he held at the time of his death. He was also president of the Manchester Association for the Help of Retarded Children in 1970. Dr. Prignano died November 9, 1976, at the age of 61.

Riendeau, Fernand M., University of Paris, 1927. Dr. Riendeau was a general practitioner and psychiatrist in the Litchfield area until his retirement. During World War I he served as a hospital apprentice in the U.S. Navy. He was a member of the Litchfield County Medical Association and the Connecticut State Medical Society. Dr. Riendeau died September 26, 1976, at the age of 81.

Thalberg, Reuben, Yale Medical School, 1926. Dr. Thalberg was a general practitioner in Southington. He was a fellow of Brandeis University, established the Reuben CE Thalberg Foundation in 1954 and was an active contributor to the Yale School of Medicine and Yale University. He was a member of the American Medical Association, the Connecticut State Medical Society and was affiliated with numerous masonic organizations in the Southington area and Meriden. Dr. Thalberg died September 13, 1976, at the age of 73.

Von Salzen, Charles F., College of Physicians & Surgeons, 1936. Dr. Von Salzen was a psychiatrist in the Hartford area since 1947. He served in the U.S. Army from 1941—1946. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Von Salzen died October 23, 1976, at the age of 67.

Wiepert, William M., Yale School of Medicine, 1937. Dr. Wiepert was a general practitioner and was Avon's medical examiner, health officer and school physician for many years, prior to his retirement in 1975. He was also a veteran of World War II, and a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Wiepert died October 21, 1976, at the age of 64.

Woodward, Joseph C., Physicians & Surgeons, 1935. Dr. Woodward was a Surgeon in the Old Lyme area for many years and was a direct descendent of Thomas Hooker, founder of Hartford. He was a diplomat of the National Board of Medical Examiners and a former president of the New London branch of the Connecticut Cancer Society. He was a veteran of the Navy Medical Corps, a member of New London County Medical Association and the Connecticut State Medical Society. Dr. Woodward died August 22, 1976, at the age of 67.

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PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiry of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511, (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine*.

PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

Internal Medicine: Available August 1977. New Haven native. Completing active duty in U.S. Army. M.D. from Duke. Internship and residency at Presbyterian-University of Pennsylvania Medical Center. Desires group practice. David A. Levitin, M.D., Department of Internal Medicine, Walson Army Hospital, Fort Dix, NJ 08640.

Internal Medicine: Group practice. Available July 1977. Completing training at Stamford Hospital. 28 years old. M.D. from George Washington University. Board eligible 6/77. Complete resume on file at CSMS. IM—MMD.

Internal Medicine: Available July 1977. Desires Fairfield County area. M.D. from Albert Einstein Medical College. Trained at Montefiore. Board eligible. Desires group or associate practice. Steven Meyerson, M.D., 155 South Broadway, Tarrytown, NY 10591.

Internal Medicine (Nephrology): IM with acute and chronic dialysis. Completing fellowship at Mass. General. Available July 1977. Princeton grad. M.D. from Harvard. 28 years old. Group or associate practice in large community. Robert J. Goldstein, M.D., 108 Presidents Lane, Quincy, MA 02169.

Internal Medicine: Connecticut license. Available now. 46 years of age. M.D. from University of London. Fellow of the Royal Society of Medicine. (FLEX in 1971.) Has been associated with public health clinics in New York State. Interested in Public Health, institutional or industrial positions. David C. Hutfield, M.D., Box 963, Norwich, CT 06360.

Internal Medicine (Cardiology): Board certified. 35 years old. Completing fellowship at R.I. Hospital in Providence. Available June 1977. Trained at Stamford Hospital, CT. T.B.N. Kumar, M.D., Rhode Island Hospital, Providence, RI 02902.

Internal Medicine (Oncology): Available July 1977. Board eligible. FLEX. Completing training at Queens Hospital, Jamaica, NY; 33 years old. M.D. from Taipei Medical College, Taiwan. Chia Y. Chou, M.D., 86-31 57th Ave., Elmhurst, NY 11373.

Internal Medicine: 31 years old. Connecticut license. Available August 1977. Two years in pediatrics at Albany Medical Center. Completing program in internal medicine at St. Mary's Hospital, Waterbury. Wishes to remain in Connecticut. Ronald D'Andrea, M.D., 224-E Oakville Ave., Waterbury, CT 06708 (1-573-9795).

Internal Medicine: Connecticut license. FLEX. Available July 1977. Board eligible. Desires group practice. Has had ER experience. Resume on file with CSMS. IM-GMD.

Internal Medicine (Cardiology): Available May 1977. Interested in invasive and non-invasive cardiology. Completing fellowship at Cedars—Sinai Medical Center in Los Angeles. M.D. from University of Pittsburgh. Thomas S. Brodie, M.D., 503 No. La Jolla Ave., Los Angeles, CA 90048.

Internal Medicine (Cardiology): Group, associate or institutional practice desired. Board certified. K.P. Channabasappa, M.D., 3241 Pickwick Circle, E #22, Taylor, Michigan 48180.

Internal Medicine (Gastroenterology): Available late summer 1977. Board certified. Group or associate practice desired. M.D. from George Washington University. Completing fellowship at U.C.L.A. Marc K. Binder, M.D., 20820 Anza Ave., #204, Torrance, CA 90503.

Internal Medicine (Gastroenterology): Available July 1977. Seeks group practice. M.D. from NYU Medical School. Fellowship at St. Luke's Hospital in NYC. 30 years old. Board eligible. Elliot H. Borak, M.D., 505 E. 14th Street, New York, NY 10009.

Internal Medicine (Cardiology): Available July 1977. Degree from University of Manchester, England. Residency at Stamford, CT. Completing fellowship at Nassau County Medical Center. Desires group or associate practice. Charles I. Okonkwo, M.D., 410 Maryland Ave., Staten Island, NY 10305.

Internal Medicine: Presently available. Connecticut license. FLEX. Board eligible. Presently in practice. Wishes to return to Connecticut. Trained at Norwalk Hospital. J.K. Patel, M.D., c/o R.D. 1, Rt 57, Box 1., Washington, NJ 07882.

Internal Medicine: Connecticut license. Desires institutional location. Interned at Danbury Hospital. Available July 1977. R.C. Patel, M.D., 5 Franklin Avenue, Apt. C-7, Nutley, NJ 07110.

Internal Medicine: Desires group or associate practice in medium or small community. M.D. from Tufts. Internship and residency at Medical Center of Western Massachusetts. Available in July 1977. Personal interview can be arranged. Board eligible. Robert P. Rosenthal, M.D., Lake Paradise, Monson, MA 01057. (413-267-3861).

Internal Medicine (Pulmonary): Presently in US Navy at National Naval Medical Center, Bethesda. ABIM 1973. Desires to do pulmonary consults, intensive respiratory care, fiberoptic bronchoscopy and pulmonary function lab. Available July 1977. Brown graduate. M.D., from Univ. of VA. Internship and residency at Albany Medical Center. John D. Royall, M.D., 9923 Lake Landing Road, Gaithersburg, MD 20760.

Internal Medicine (Cardiology): Available August 1977. Board certified. Desires group or institutional practice. Interested in clinical teaching position. M.D. from Wayne State. Fellowship at Iowa. William S. Sarnat, M.D., 711 Keswick Drive, Iowa City, IA 52240.

Internal Medicine (Cardiology): Hospital or group practice desired. ABIM taken in 1976. Available July 1977. M.D. from Univ. of So. California. Internship and residency at Georgetown. Fellowship at University of Vermont. 31 years old. Michael Schwartz, M.D., 406-A Dalton Drive, Winooski, VT 05404.

Internal Medicine (Pulmonary): Available July 1977. M.D. from Boston University Internship and residency at George Washington University. Fellowship at North Carolina. Group practice desired. Ronald J. Scott, M.D., 420 Overland Drive, Chapel Hill, NC 27514.

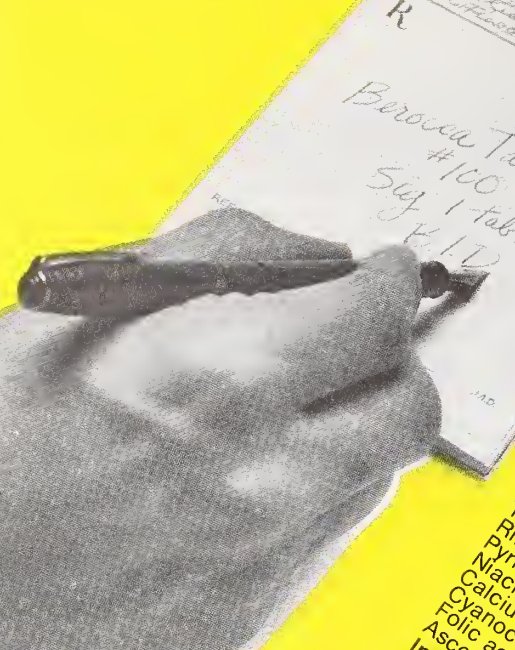
Internal Medicine: Available July 1977. Board eligible. Completing program at St. Mary's Hospital, in Waterbury. Complete resume on file at CSMS. IM-S.

Internal Medicine: Board certified. 30 years old. Presently in practice but wishes to return to the East. Group or associate practice. M.D. from Downstate New York. Interned at Kings County and residency at Tucson. Available on or before July 1977. Jeffrey I. Selwyn, M.D., 7111 Pampa Place, Tucson, AZ 85704.

Pediatrics: (Allergy) Available July 1977. Board certified. Interested in teaching and affiliation with group or associate type practice or institutional position. 31 years old. Presently in service. M.D. from Jefferson. Residency at New York Hospital. Fellowship at University of Colorado. Michael Z. Blumberg, M.D., 701 North Lincoln Street, O'Fallon, IL 62269.

Pediatrics: Board eligible. Presently on active duty. Available August 1977. Bowdoin graduate. M.D. from Duke. Residency at Children's Hospital in Pittsburgh. 30 years old. Neal G. Bornstein, M.D., 89 Totten Street, Ft. Leonard Wood, MO 65473.

(Continued to next page)



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Pediatrics: Board eligible. Completing tour of duty with the Navy. Available July 1977. Amherst graduate. M.D. from S.U.N.Y., Downstate. Residency at Roosevelt Hospital in NYC. Desires group practice. Wife completing Ph.D. Would desire teaching opportunity. Ronald S. Bashian, M.D., 2521 South Meridian Dr., Great Lakes, IL 60088.

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Pediatrics: Board eligible. Completing training at R.I. Hospital. M.D. from Tufts. Solo, group or associate practice will be considered. 28 years old. Available July 1977. Alfred Dushman, M.D., 3595 Post Road, Apt. 13-301, Warwick, RI 02886.

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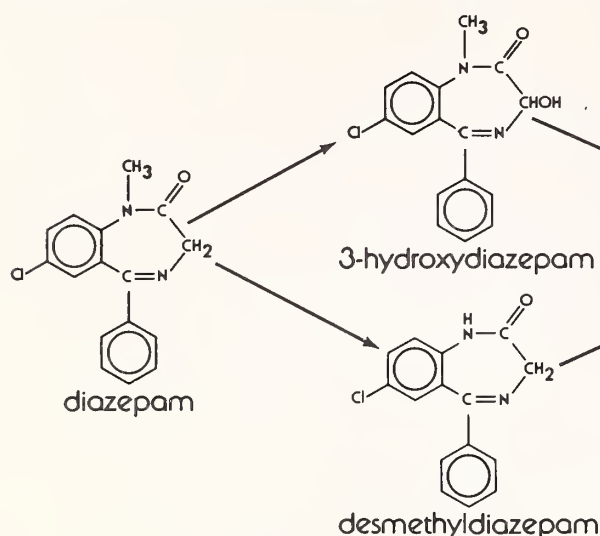
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Current Surgical Management of Hyperparathyroidism

Henry Mannix, Jr., M.D.

ABSTRACT—Primary hyperparathyroidism is being diagnosed with increasing frequency, since the use of the autoanalyser became widespread. It is now possible to make the diagnosis with considerable certainty. The major problem comes in identifying the pathology and in deciding whether the pathology is adenoma or hyperplasia.

Surgery, when properly performed, is successful in 90%-95% of patients undergoing primary operation. Tertiary hyperparathyroidism is also being seen more frequently due to better management of renal disease.

This review discusses some of the current thinking regarding proper management in these patients.

Incidence

Primary hyperparathyroidism is a disease of uncertain incidence, since it appears that a significant number of patients with hypercalcemia do not have any symptoms that can initially be related to the hypercalcemia. The first apparent case of primary hyperparathyroidism was reported in 1705,¹ but the disease never was clearly identified until the late 19th century, and it is quite apparent from a review of the literature that the incidence of this disease has become far greater since the introduction of the autoanalysers to many hospitals throughout the world. The Mayo Clinic, which has the largest collected series of patients with primary hyperparathyroidism, has been doing an on-going study to determine the changes in patients with hypercalcemia. In 1971,² they reported a 30-month study in which 400 patients were studied for possible defects in calcium metabolism. 191 were explored and 171 were found to have significant parathyroid pathology. There were 20 negative explorations. There were 147 patients not explored with a tentative diagnosis of asymptomatic hyperparathyroidism.

In another article from same group³ reported the five-year period from 1968 to 1972, in which they had 475 patients who were operated. In a group of patients who had been followed over a five-year period, who were not operated because they were asymptomatic, it was found that approximately 20% developed symptoms that could be related to parathyroid abnormalities.

Williamson and Van Purnen in 1974⁴ reported a study from the University of Missouri in which 4227 patients had been screened. Of this group of patients, only six patients were hypercalcemic and two patients were normocalcemic, but presumed to have hyperparathyroidism. Only three patients were operated upon. It was their feeling that extensive screening could not be justified on the basis of its great cost in relation to the yield of patients with significant disease.

Another area of considerable interest is the patient who appears to have hyperparathyroidism on the basis of renal or bone pathology, but in whom the calcium levels are persistently normal or, as in one reported case, below the average normals for that clinic. It appears that these patients can be better screened at this time by using the parathyroid hormone immuno-assay studies.⁵

Diagnosis

The classic symptoms of hyperparathyroidism have always been considered to be related to kidney and bone pathology, and in the older literature, it was quoted that as many as 95% of patients with hyperparathyroidism would have either bone or renal pathology or both. This view has been changed in recent years and it appears that patients with primary hyperparathyroidism may exhibit significant ulcer disease, pancreatitis, and psychiatric changes. It is of interest that a recent survey of parathyroid disease in children⁶ seemed to point out that these patients tended to have emotional changes, rather than renal or bone pathology, as the presenting complaint.

Dent,⁷ in England has postulated, and others appear to agree, that patients with higher calcium levels are more likely to have bone pathology and are more likely to have large tumors. This opinion was substantiated by Purnell² and the Mayo Clinic group, who studied 83 patients and were able to note a positive correlation between the serum PTH levels, the calcium levels, and the size of the tumor.

The diagnosis of primary hyperparathyroidism has become considerably easier with the advent of the radio-immuno-assay of parathormone. Although there are some problems to be worked out of this test, it appears that individuals who have a normal or high serum calcium in association with a normal or high parathyroid hormone immuno-assay are extremely likely to have parathyroid pathology. The older tests, such as the serum calcium, serum glucagon, phos-

HENRY MANNIX, JR., M.D., Director of Surgery, Saint Francis Hospital; Associate Professor of Surgery, University of Connecticut Health Center.

phate deprivation, and the like, are less used today and are definitely of less importance than they were in bygone days.

Localization

The major challenge in parathyroid surgery today is the localization and identification of the pathology, either in the neck or the mediastinum. It is the experience of most surgeons knowledgeable in the field of parathyroid exploration that a careful neck exploration will identify the abnormal glands in well over 90% of neck explorations.²⁻⁸ The problem arises in the 5% to 10% of patients where the neck exploration is either negative or where the patient has been previously explored, and now has either recurrent hyperparathyroidism or has never been properly treated.

Approximately ten years ago, Potchen⁹ popularized the idea of using tagged methionine with selenium-75 to selectively identify parathyroid tissue. There was initial enthusiasm for this technique. However, it became apparent that this was useful only where the tumor was relatively large, that is, more than 1 cm. in diameter, and it is well known that these tumors are usually easy to identify at operation.

The next technique^{10, 11} that was developed for the identification of parathyroid tissue was the use of vital dyes, such as toluidine blue. Toluidine blue is extremely accurate in identifying tissue, but it has a significant drawback in that it may cause cardiac arrhythmias, even in normocalcemic individuals, unless strict attention is given to the dose of the dye. Also, there is a definite time relationship, in that the dye must be given shortly prior to surgery. It appears to have achieved a limited usefulness in this field.

The use of selective venous catheterization, in addition to x-ray studies of the vessels of the neck, has become quite popular. The group at the National Institutes of Health appears to have the largest experience in this area.

Bilezikian and associates¹² reported in 1973 the combined experience of the NIH, the MGH, and Walter Reed. They studied 94 patients and had an accuracy of 82% in adenomas and 74% in patients with hyperplasia.

This was done using selective venous sampling. If large vein sampling was done, the accuracy rate dropped off markedly. Davies¹³ from the University College in London, in a smaller series, had somewhat the same results as previous authors, and both of these groups felt that this technique should be used primarily in patients who had previous neck exploration. More recently, Doppman,¹⁴ from the NIH reported the use of these techniques in the identification of mediastinal parathyroid glands.

Thermography was reported as being useful in 1972¹⁵ in 18 out of 29 patients. In 17 of 18, the tumor

was found where it had been identified. The smallest tumor found was 0.3 cm. x 0.3 cm. This technique has not been widely reported subsequent to 1972 and, considering the size of most parathyroid tumors, seems to be of questionable value.

The Japanese in 1974¹⁹ reported using thyroid lymphography. This also has not been substantiated to my knowledge by other authors.

Pathology

The pathology of primary hyperparathyroidism is clearly in a changing state. Most of the older papers estimated that there were approximately 85% of patients with solitary adenomas, possibly 5% with more than one adenoma, 8% or 9% of patients with hyperplasia, and somewhat less than 1% of patients¹⁷ with clearly proven carcinoma.

Paloyan,¹⁸ Ballinger,¹⁹ Esseltyn²⁰ in the last several years have presented data which would indicate that the incidence of hyperplasia, at least in the cities of Chicago, St. Louis, and Cleveland is much higher than in other parts of this country. In Esseltyn's report, he noted that in the last 110 neck explorations 55 patients had hyperplasia as the cause for their symptoms. On the other side of the coin, however, the Mayo Clinic group still reports a vast preponderance of patients with solitary adenomas. It has been the experience of the author in a personal experience of somewhat over 80 cases that the incidence of hyperplasia is less than reported from the midwest.

It is hard to be certain about the incidence of parathyroid carcinoma. In 1973,¹⁷ in a collected series in Massachusetts General Hospital 73 patients were found to have verified cancer. Recently, there was a case in Hartford of a woman with a long history of hyperparathyroidism whose terminal event was the development of a large invasive parathyroid neoplasm in the neck and mediastinum. She had had three previous neck explorations over a 30-year period prior to the final event.

Surgical Therapy

As in the incidence of hyperplasia versus adenoma, the proper therapy of primary hyperparathyroidism is controversial. Most authors advocate identifying all four parathyroid glands; some think that this is not possible or would be extremely time-consuming. The therapy of patients who clearly have hyperplasia is quite straightforward in that everybody would advocate resecting three-and-a-half glands. The main difference of opinion arises in the patient who has clearly one adenoma and possibly no other evidence of pathology in the remaining three glands. Paloyan¹⁸ has advocated for some time routine subtotal parathyroidectomy, even in this situation. Most recently, Ballinger¹⁹ has come to advocate this technique as a way of

preventing possible recurrent hyperparathyroidism. Other authors feel that this is too radical treatment and may lead to an incidence of hypoparathyroidism. Black,²¹ with a large experience, advocates identifying all four glands, but does not favor subtotal parathyroidectomy. In a situation where it is not possible to identify all of the pathology, he advocates doing a thyroid lobectomy on the side where one cannot identify parathyroid tissue, if two normal parathyroid glands have been identified on the contralateral side. Palmer²² and associates from the University of Toronto reported in 1975 an experience of 250 cases. There was a 15% incidence of multiple gland involvement and they advocated biopsying all glands, even the apparently normal ones. It is the author's opinion that where the surgeon can identify clearly an abnormal gland that is consistent in size with the level of the serum calcium it is reasonable not to damage the other parathyroid glands by biopsy or subtotal excision.

Tertiary Hyperparathyroidism

The syndrome of autonomous or tertiary hyperparathyroidism has been receiving more attention with the advent of widespread use of dialysis and renal transplantation^{23, 24, 25}. A significant number of patients who have been on long-term dialysis will develop signs of hypercalcemia, frequently involving the bones. In addition, it was the experience at the New York Hospital that some patients post-transplant would develop hypercalcemia, which could threaten the transplanted kidney. It appears that approximately 10% of patients²⁴ on chronic dialysis may require some form of surgery to handle the symptoms of hypercalcemia. Most of these patients can be handled medically. The surgical therapy of these patients is relatively straightforward, since the glands are usually large and easily identifiable. Most authors seem to prefer subtotal, rather than total, parathyroidectomy in these patients with chronic renal disease.

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A Family Outbreak of Trichinosis in Connecticut

Richard V. Lee, M.D. and Richard J. Mangi, M.D.

ABSTRACT—Four of seven family members eating homemade, uncooked pork sausage developed clinical, serological or both manifestations of trichinosis. The epidemiology, pathogenesis, and clinical manifestations of *T. spiralis* infection are briefly reviewed.

Human infection with *Trichinella spiralis*, once affecting about 15-20% of the United States population¹⁻³ is now rather a rarity in Connecticut. During the five year period, 1970-1974, the Center for Disease Control⁴ reported 523 acute infections throughout the United States and 33 acute infections in Connecticut (Table 1). Despite improved animal husbandry and feeding practices with a consequent reduction in infestation of meat, particularly pork, occasional outbreaks of trichinosis continue to occur.¹⁻³ The purpose of this paper is to present the findings of an outbreak of *T. spiralis* infections in Connecticut due to inadequately cooked, homemade pork sausage, and to review the important clinical manifestations of trichinosis.

Table 1

Year	Connecticut	U.S.A.
1970	5	109
1971	4	103
1972	4	89
1973	9	102
1974	11	120
	33	523

Cases of Trichinosis Reported to the CDC (4)

Case Reports

Patient #1 (Table 2) is a 31-year-old housewife admitted to the hospital on 3/29/75 because of swelling and protrusion of both eyes. Seven days before admission she noted swelling of her eyelids, purulent discharge from the eyes and headache. Two days before admission she developed fever to 102° F. and retro-orbital pain. The patient had diarrhea for 2-3 days before admission. Approximately three weeks before admission the patient ingested homemade, uncooked sausage.

On admission the temperature was 103° F. The ocular tensions and exophthalmometry were normal. There was marked chemosis of

the conjunctivae and edema of both eyelids, giving the effect of ptosis. The extraocular movements were intact except for some slight restriction of downward motility of the right eye. Examination of the optic fundi, pupils, and visual fields was within normal limits. The thyroid was not palpable. The cardiac rhythm was regular; there was an S-4 gallop at the apex but no murmurs were heard. The rest of the examination was unremarkable.

Admitting laboratory data included a white blood count of 8,100/mm³ with 79% segs, 5% bands, 16% lymphs, 2% monos, 1% eosinophils. The hematocrit was 48%. The T-3 uptake, T-4, and thyroid scan were normal. Antinuclear antibody and VDRL tests were negative; and serum protein electrophoresis was within normal limits. All x-rays and other chemistry tests were unremarkable.

The patient continued to be febrile and to complain of eye pain and diarrhea despite treatment with antibiotics. On 4/2/75 the white blood cell count was 9,800/mm³ with 26% eosinophils. The erythrocyte sedimentation rate was 15 mm/hour. Because of the history of ingestion of uncooked pork sausage and the coincident occurrence of a similar disease in her sister-in-law who also ingested the pork sausage, steroids were begun on 4/2/75. Within 24 hours after starting steroids the patient became afebrile and her ocular symptoms improved dramatically. The Bentonite flocculation test for trichinosis was negative on 4/3/75. She was discharged feeling well on 4/6/75. Over the ensuing several weeks the corticosteroids were tapered and finally discontinued.

Patient #2 (Table 3), patient #1's sister-in-law is a 36 year old housewife who was admitted on 4/2/75 with periorbital edema and fever of six days duration.

About three weeks before admission the patient and her family ate the same uncooked, homemade pork sausage as patient #1. About two days after eating the sausage she developed abdominal discomfort and nausea, associated with cramping but no diarrhea or vomiting, which persisted until shortly before the time of admission. Six days before admission she noted the onset of puffiness about her eyes, headache, and fever to 101° F. Three days before admission she was seen in the Emergency Room with periorbital edema and a temperature of 100.4° F. by mouth; the white blood count was 8,800/mm³ with 5% eosinophils. On the day of admission she had a temperature of 101.6° F. by mouth and a pulse of 140/minute. Examination was remarkable for marked conjunctival edema and injection with prominent periorbital edema. There were no splinter hemorrhages or petechiae and no localizing neurologic signs. There were no abnormal heart sounds but she did have a persistent tachycardia. The white blood count was 6,900/mm³ with 13% eosinophils and 2% eosinophil bands. The hematocrit was 41%; the erythrocyte sedimentation rate 34 mm/hour and the total eosinophil count 1,130/mm³. Thyroid function tests, protein electrophoresis and muscle enzymes were all within normal limits. Examination of stool for ova and parasites and the VDRL, ANF, and LE tests were all negative. All x-rays and other chemistry tests were unremarkable. The patient was treated with bed rest and aspirin. During her hospitalization she developed transient diplopia with minimal weakness of the extraocular muscles and pain with eye movement. She was discharged on the fourth hospital day feeling much better and with almost complete resolution of her periorbital edema. Five days after discharge she had another episode of fever to 101° F. with painful muscles. Examination demonstrated some minimal periorbital edema, a splinter hemorrhage under the left third fingernail, a petechia

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Table 2

Date	WBC	EOS%	ESR	Patient #1		CPK	History Signs and Symptoms
				Bent. Flocc. Titer	SGOT		
3/8-3/15							Ate uncooked pork sausage
3/21							Onset of periorbital edema and pain
3/27							Temperature 102° & diarrhea
3/29	8,100				17		Temp. 103°; Marked chemosis; Periorbital edema; mild proptosis.
4/2	9,800	26	15	Negative			Thyroid function tests normal Started on Steroid with rapid resolution of findings.

Table 3

Date	WBC	EOS%	ESR	Patient #2		CPK	History Signs and Symptoms
				Bent. Flocc. Titer	SGOT		
3/8-3/15							Ate uncooked pork sausage
3/15/75							Onset of nausea & abdominal cramps; persisted for about 2 weeks
3/28							Periorbital edema; neck & back pains
3/31	8,800	5					Same as above
4/2	15,100	11		Negative			T.=100.4 orally T.=101.6
4/3	6,900	15			32	40	Periorbital edema
4/4	7,300	19	29				T.=101; improving
4/8				1:5			T.=100.4
4/11	11,600	39	50	1:5	38	156	Muscle Ache
4/21				1:320			Feeling Better
5/12				1:160			

Table 4

OTHER MEMBERS OF THE FAMILY WHO ATE THE SAUSAGE

Relations	Symptoms	Bentonite Flocculation Test & Date	
Brother	None	1:40960	4/18/75
Mother	None	Negative	4/21/75
Aunt	None	Negative	4/21/75
Husband of Patient #2	Periorbital edema; Muscle aches; Fever	Refused Examination and Testing	
Daughter of Patient #2	None (Pregnant)	Negative	4/8/75

on the right conjunctiva and some tenderness of the quadriceps muscles bilaterally. Neurological examination was within normal limits. The SGOT was 38 (slightly elevated) and the CPK was 156 (twice normal). The erythrocyte sedimentation rate was 50 mm/hour and there were 37% eosinophils in a total white blood count of 11,600/mm³.

One week later her symptoms had cleared completely. The Bentonite flocculation tests for trichinella antibodies are given in Table 3.

Epidemiology and Illness in Other Family Members

When the diagnosis of trichinosis was established, other members of the family who had eaten the sausage were tested for trichinella antibodies. The results of these tests are shown in Table 4. Unfortunately, the sausage had been discarded by the husband of patient #2. The sausage had been made from uncooked pork bought from several meat stores.

The two patients and patient #2's husband and brother consumed

larger amounts of the sausage than other members of the family. Patient #2's pregnant daughter, mother, and aunt had eaten small amounts of the sausage and had no clinical or serologic evidence of disease. Although the family had been making sausage for some years there had never been any illness associated with its consumption.

Patient #2's husband refused any medical examination. On April 14, 17 days after his wife's periorbital edema had begun, he was reported to have swelling about his eyes, muscle aches, and fever. He was apparently ill for several days but made a complete recovery without any medical attention. One of the brothers of patient #2 apparently did not have symptoms but had a Bentonite flocculation titer of 1:40960. This individual was never examined.

Discussion

Epidemiology:

T. spiralis is a parasite of many omnivorous and carnivorous animals. It is especially common in animals that feed on infected wild animal carcasses, uncooked garbage, or slaughterhouse scraps such as rats, pigs, bears, and man.¹⁻⁸ Since the adoption of state laws requiring the cooking of garbage fed to hogs, the incidence of both swine and human disease has fallen dramatically.¹⁻³ In the 1930's it was estimated from autopsy studies that one in every six people in the United States was infected during their lifetime. Recent reports¹⁻³ estimate that the rate of infection has declined to one in 25. However, the cases reported here illustrate the need for continued vigilance and caution. Cooks should be instructed and reminded to store meat at cold temperatures and to thoroughly cook pork and any meat from an omnivorous or carnivorous game animal. Trichinosis has been reported following ingestion of meat from bears and walrus. Freezing meat at temperatures below -37°C. will kill most of the encysted larvae.^{2,7} Cooking meat so that a uniform temperature greater than 58.3°C. is maintained for several minutes until the center is free from any trace of pink color will kill all of the encysted larvae.²

Clinical Pathophysiology:^{7,8}

Infection begins when the larvae excyst after the improperly prepared meat is digested. The larvae penetrate the small intestinal mucosa and rapidly mature into adult worms. The consumed larvae can mature, reproduce and generate tissue-invasive larvae within five days after ingestion. The intestinal phase of the infection persists as long as fertile adult female worms remain in the intestine and intestinal mucosa. The intestinal phase in humans has been known to occasionally last as long as 54 days but the average duration is usually shorter.

The tissue invasive larvae enter the lymphatics of the intestinal mucosa and the bloodstream. The larvae escape from the circulation by penetrating the capillaries and invading muscle fibers. Larval egress from the capillaries is accompanied by an inflammatory re-

sponse and by leakage of plasma and red blood cells. The larvae are capable of invading almost any tissue; however, they survive and are potentially infective only in striated muscle.

Clinical disease occurs during both the intestinal phase and the tissue invasion phase of the infection. However, many infections are mild or subclinical, perhaps reflecting small numbers of viable larvae in the infecting inocula or effective host resistance. It is distinctly unusual to see clinical trichinosis more than once in the same individual, but it is difficult to tell if the absence of second episodes is due to increased host resistance or improved common sense in meat handling.

Most physicians are unaware of the intestinal phase of the infection because the symptoms it produces are non-specific. Abdominal cramps and diarrhea are most common. Nausea, vomiting, constipation and low-grade fever occasionally occur. Eosinophilia is usually absent or minimal during the intestinal infection phase.

When invasive larvae begin circulating and invading tissue, the classical syndrome of trichinosis emerges: Fever, eosinophilia, and periorbital edema. The severity of symptoms will vary according to the intensity of the infection and the host response. Fever and eosinophilia are consistently seen when the infection is sufficiently intense to cause any symptoms. Eosinophilia frequently occurs in asymptomatic cases. The eosinophilia usually develops rapidly after the first week of the tissue invasion phase and reaches its peak, anywhere from 5-90% of the total white blood cell count, by the third or fourth week of symptoms. Leukocytosis is common, but not invariably present. Periorbital edema is rarely absent in patients with symptoms of infection. Edema of the eyelids and puffiness about the eyes may begin as soon as 7-10 days after ingesting infected meat, but symptoms and signs of tissue invasion generally appear in the third week of the infection. The periorbital edema is presumed to be due to the small vessel vasculitis that accompanies the migration of tissue invasive larvae. Similarly, the conjunctival petechiae and subungual splinter hemorrhages which are sometimes seen during this phase of the disease are thought to be caused by the migration of larvae out of the capillaries.

The larvae have a predilection for striated muscles. Invasion of muscle fibers by large numbers of larvae may produce myositis. The patient may complain of photophobia, diplopia, and discomfort with moving the eyes. Muscle pain can be severe and may be associated with muscle tenderness. The myositis usually peaks during the third and fourth weeks of infection and produces rises in muscle enzymes. Myocarditis may also occur and, in severe cases, congestive heart

failure, conduction abnormalities, and arrhythmias may be present.

Other manifestations of the tissue invasion phase include skin rash, urticaria, and central nervous system abnormalities including meningoencephalitis, with larvae in the cerebrospinal fluid and local granulomas or inflammation producing symptoms and signs consistent with cerebral vascular accident or brain tumour. Pulmonary edema and bronchopneumonia may also occur. Hypoproteinemia due to loss of plasma into tissues may occur in severe infections. Fortunately these complications and death are vanishingly rare.

Diagnosis:^{6,7}

The diagnosis in a florid case with a classic dietary history, symptoms and signs and laboratory findings is never difficult. Polymyositis and periarteritis nodosa may mimic trichinosis by the presence of fever, myalgia and eosinophilia. There are several serologic tests to aid in the diagnosis. Of these, the Bentonite flocculation test is the most widely used. The Bentonite flocculation test usually becomes positive in the third or fourth week of infection. A change from a negative to a positive test is significant. As illustrated by patient #2, the Bentonite flocculation test may be negative at the time the patient presents with symptoms but can convert to positive within a week. Skin testing using antigens from trichinella larvae has been used. However, because of a lack of specificity, the skin test is not reliable and not recommended for use.

Examination of the stools for adult trichinella worms is regularly unsuccessful. During the tissue invasion phase, circulating larvae may be observed in centrifuged blood or cerebrospinal fluid.

The definitive diagnosis is accomplished, when necessary, by biopsy of an affected muscle. The deltoid or gastrocnemius muscles are usually satisfactory sites for biopsy. A small piece of unfixed muscle is crushed between two microscope slides. Larvae can be seen under low power. Examination of fixed tissue may be tedious and non-productive except in the heaviest of infections. In light infections, mechanical and enzymatic disruption of the biopsy specimen followed by centrifugation and examination of the sediment may reveal larvae. Biopsy is best attempted during the fourth week of infection or when the patient has clinical

evidence of muscle invasion. Tender, aching muscles are more likely to yield a positive result than muscles normal on examination. In our patients the combination of clinical findings and history and serological evidence for trichinosis obviated the necessity of muscle biopsy.

*Treatment:*⁶⁻⁸

In patients with mild or moderate disease, symptoms begin to diminish by the fifth or sixth week of infection although the eosinophilia may persist for months. Treatment should be individualized. The vast majority of patients require only supportive care, bed rest, and simple analgesic and anti-inflammatory medication such as aspirin. In the usual infection, the disease is uncomfortable but benign, and the prognosis excellent even without treatment. Severe infections producing intense edema and inflammation of the muscles and central nervous system should be treated with corticosteroids. An initial dose of 20-40 mgms. of prednisone or an equivalent can be tapered rapidly to the lowest dosage that alleviates symptoms and then discontinued usually within 2-3 weeks after starting therapy. Steroids suppress the inflammatory response to the parasite but do not affect the fecundity of the adult or the viability of the encysting larvae.

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Complications and Pitfalls of Subclavian Vein Cannulation: An Update

Max Schapira, M.D., Wilhelm Z. Stern, M.D. and Elizabeth A. Frost, M.D.

In 1967 two of the authors¹ published a paper in which they took note of the popularity of central venous pressure (CVP) monitoring. They described different techniques for the placement of CVP catheters into the central portion of the venous system and then presented four case reports which demonstrated the complications occasionally encountered when intravenous catheters were inserted into the subclavian vein.

The authors felt quite strongly that although complications could occur in all techniques of CVP cannulation, the more severe and more frequent complications were encountered with the subclavian vein approach; they therefore suggested that CVP monitoring by cannulation of the subclavian vein be abandoned.

It is obvious, however, that insufficient attention was paid to our suggestion, as many reports of complications due to subclavian vein cannulation have been published since 1967.

In the October 12, 1970 issue of the JAMA, alone there were several letters to the editor reporting the following complications:

1. The occurrence of a hydrothorax on the right side from a subclavian vein catheterization.²
2. A case of hydromediastinum on the right side after subclavian vein catheterization.³
3. Occurrence of cardiac syncope after extravasation of I.V. physiological saline through the wall of a right subclavian vein.⁴
4. Knotting of a catheter, introduced into a subclavian vein.⁵ (This last complication, admittedly, is one that can occur with any central or peripheral vein catheterization.)

In October 1970 Johnson⁶ et al described in the Mayo Clinic Proceedings two major complications in a series of 120 percutaneous subclavian vein catheterizations. One of these complications was a case of air embolism and the other one was an obstruction of the superior vena cava.

Another complication, arterial puncture during left subclavian vein catheterization with a fatal outcome

was reported in a letter to the Editor of the JAMA, dated July 5, 1971.⁷

In June 1972 Borja⁸ published a review article on the then current status of subclavian vein cannulation. The rate of complications ranged from 0.4% to 9.9%. There were 14 deaths directly connected to this procedure. The most common complications encountered were pneumothorax, hemo- and hydrothorax and air embolism. Air embolism was responsible for the greatest number of deaths.

In January 1974, Bernard and Stahl,⁹ from the New York University Medical Center, reported, in the New York State Journal of Medicine, a case of mediastinal hematoma, a rather unusual complication, following a subclavian vein catheterization. Fortunately, the patient recovered and left the hospital in good condition.

Another rare complication was reported by Klipper¹⁰ et al in a letter to the JAMA of May 6, 1974. They reported that a cuff of an endotracheal tube was perforated when a CVP catheter was introduced via the right subclavian route.

In spite of all the evidence that subclavian vein cannulation is accompanied by such a high complication rate, this technique has retained its popularity and is even today probably the most commonly used technique for central vein catheterization.

In our own institutions (Morrisania City Hospital and Jacobi Hospital) subclavian vein cannulation is still carried out, although not as frequently as before, and the following incidents were noted on X-ray control:

Case 1

A 36 year old male with a stab wound of the abdomen had a CVP catheter inserted into the right subclavian vein. The catheter perforated the subclavian vein into the right pleural cavity, producing a hydrothorax. Some blood was also inadvertently administered into the right pleural cavity, producing a partial hemothorax. The patient required a thoracotomy for evacuation of the right pleural space and thereafter had an uneventful recovery. (Figure 1)

Case 2

A catheter was inserted via the left subclavian vein for monitoring of the CVP in an 87 year old female. On X-ray examination the catheter was seen to be coiled in the left subclavian vein, at its junction with the innominate vein, recording totally erroneous information. (Figure 2)

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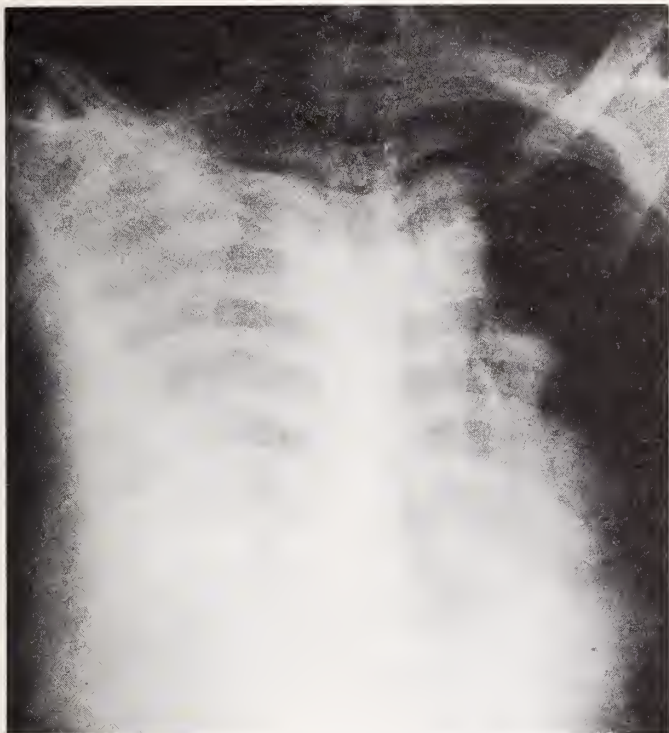


Figure 1

A central venous pressure catheter was inserted via the subclavian vein in this 36 year old male who had suffered a stabwound. The catheter perforated from the subclavian vein into the right pleural cavity, producing a hydrothorax. Part of a blood transfusion was also inadvertently administered into the right pleural cavity. The patient required a thoracotomy for evacuation of the right pleural space and recovered uneventfully.

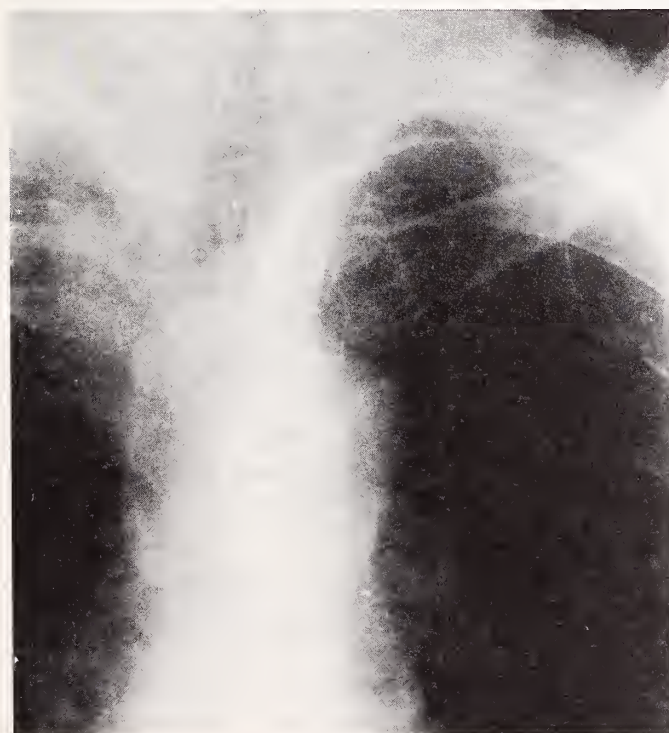


Figure 2

A catheter was inserted via the left subclavian vein for monitoring of the central venous pressure in this 87 year old female. The catheter is seen to be coiled in the left subclavian vein, at its junction with the innominate vein, serving no useful purpose.

Case 3

A 59 year old male was admitted to Morrisania City Hospital with the diagnosis of pulmonary edema. He had a CVP catheter inserted via the right subclavian vein. On X-ray study the catheter was noted to be in the right prevertebral vein. A second catheter was subsequently inserted from the left side into a satisfactory position in the superior vena cava. (Figure 3)



Figure 3

A 59 year old male, admitted with pulmonary edema, had a central venous pressure catheter inserted via the right subclavian vein. The catheter is noted to be in the right prevertebral vein. A second catheter was subsequently inserted from the left side into a satisfactory position in the superior vena cava.

Case 4

A CVP catheter was inserted into the right subclavian vein of a 62 year old male. A fragment of the catheter broke off and migrated with the blood stream into a right lower lobe branch of the right pulmonary artery. (Figure 4)

Case 5

A 30 year old male was admitted on November 2, 1974 with head trauma, having been hit by a truck. The patient was comatose and no further history was available.

Physical examination revealed a well developed well nourished male in coma, BP by palpation was 60 mm Hg, P 120/min., R 18/min., T 97°.

Examination of the head showed blood coming from both ears and nose, but no obvious laceration. Pupils reacted to light and

accommodation. Lungs were clear to percussion and auscultation. The rest of the physical examination was unremarkable. Roentgenograms of skull showed a basilar and a mid-frontal fracture.



Figure 4

Following insertion of a central venous pressure catheter in this 62 year old male, a fragment of the catheter broke off and migrated with the blood stream into a lower lobe branch of the right pulmonary artery.

Chest roentgenogram was normal. Laboratory findings showed a Na of 145 mEq/L, K of 4.4 mEq/L, Cl of 105 mEq/L, CO₂ of 16 mEq/L Hgb of 12.5 gm, Hct of 38%, wbc of 6500/mm³, glucose of 294 mg% and a negative urine report.

The patient had a subclavian CVP line inserted on the right side. Shortly afterwards he developed severe respiratory distress. Physical examination revealed the absence of breath sounds over the right hemithorax and a chest X-ray study showed a right pneumothorax with collapse of the upper and middle lobes.

A #28 chest tube was inserted through the 2nd intercostal space into the pleural cavity, the patient was intubated and placed on a volume preset ventilator. (Figure 5)

On the next day the arterial blood gases were pH 7.50, PaCO₂ 25 mm Hg, PO₂ 78 mm Hg, O₂ saturation 94%. The patient was taken off the ventilator and extubated. A carotid angiogram revealed a subdural hematoma which was surgically evacuated. After prolonged hospitalization the patient was discharged in fair condition.

Comment

Central venous pressure monitoring has become one of the most commonly used procedures in the Intensive Care Unit, the Operating Room and the Recovery Room and even on the hospital wards. Various



Figure 5

A central venous pressure catheter was inserted via the subclavian vein in this 30 year old male following head trauma. An extensive pneumothorax is seen surrounding the collapsed right upper lobe (arrows).

techniques are being used to insert the CVP catheter into a peripheral vein and thread it into the superior vena cava and the right atrium. In many institutions, cannulation of the subclavian vein by an infraclavicular technique has become the method of choice. In 1967, two of the authors recommended that other, safer techniques be used for CVP monitoring.

It is, however, quite obvious that subclavian vein catheterization has remained the most popular method for CVP measuring. The reason for this popularity apparently is the seemingly simple and safe way to insert an intravenous catheter unit into the subclavian vein.

This procedure is mostly carried out by housestaff personnel of different seniority. Frequently, it is done by junior house officers or even medical students without adequate experience in this technique. This fact alone could easily explain the complication rate ranging from 0.4%-9.9%. It seems, however, that even in the best of hands this procedure carries a definite risk, due to the proximity of the subclavian vein to structures such as the pleura, subclavian artery, carotid artery and even the pericardium.

After reviewing the more recent literature, it remains our opinion that adequate and safer methods (e.g. cannulation of jugular veins or veins of the upper extremities) for CVP monitoring are available than subclavian vein cannulation and that these safer techniques are therefore preferable.

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Nurse-Run "PAP" Smear Hospital Screening

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Although the death rate in Connecticut from carcinoma of the cervix has dropped by about 50 percent in the last 25 years, the actual incidence of this malignancy has increased somewhat.¹ The increase is due entirely to carcinoma-in-situ, an early and curable stage of the disease. It is generally felt that the increased use of the Papanicolaou test beginning about 1950 has accelerated the decline in mortality from cervical cancer which actually began before the test was introduced. Nonetheless, about 13,000 women die in the United States annually from cervical cancer and many more could be saved by early detection of carcinoma-in-situ rather than allowing the malignancy to progress to invasion.

In an attempt to increase the early detection of carcinoma of the cervix, routine "pap" smears were offered to all hospital female patients over the age of 21 at the Hospital of St. Raphael as an experiment during the period October 1, 1971 to September 30, 1972. The results of that project were sufficiently encouraging that the hospital has now made the "Pap" smear a routine procedure. It is the purpose of this communica-

tion to indicate how this was instituted in a Community General Hospital and to indicate both the problems and results encountered.

In January 1971 the Director of Medical Oncology at the Hospital, a practicing internist, proposed to the Connecticut Division of the American Cancer Society that an experimental program be instituted at a community hospital to determine whether it was feasible and worthwhile to have a "Pap" smear performed on all females admitted to the hospital in whom there was no contraindication and in whom no such similar procedure has been done in the preceding year. The program was approved and \$6,000 appropriated. It was anticipated that a major objection would come from the Medical Staff who correctly felt that "pap" smears should be done by a physician. When it was demonstrated that of an approximate population of 3,000 females eligible for a "Pap" test, only 96 "Pap" smears were done in the hospital by physicians in the preceding year for lack of chaperones, time, etc, then the medical staff unanimously endorsed the experimental project.

An educational program for the training of nursing personnel was begun September 1, 1971. The program consisted of lectures, audio-visual aids and demonstrations. A registered nurse and licensed practical nurse were primarily responsible for interviewing the patients, performing the "Pap" smear and guiding patient education and information.

All women admitted to the hospital except those admitted to the intensive care unit, the coronary unit, the obstetrical and gynecological services, and those under 21 years of age (more recently 18) were given a

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letter from the hospital administration informing them of the availability of the routine "Pap" smear test. At this time the patient also received literature from the Cancer Society describing the nature and importance of the "Pap" smear and directions for breast self-examination. The nurse then visited each patient and carefully explained the "Pap" smear, its value and answered any questions associated with this. "Pap" smears were performed on all of those patients admitted for routine surgery who gave their permission. Patients admitted to the hospital on an emergency basis required a physician's order for the test. This presented the first major problem in that the medical service census was so high that there were periods when only emergencies were admitted. It was finally decided at the end of the year to change the procedures so that the nurse was allowed to use her judgement except in those cases where the physician specifically indicated he did not wish a "Pap" smear. All patients were encouraged to have a complete pelvic examination by their private physician whenever possible and were told that the "Pap" smear was not an adequate substitute for a full pelvic examination by an experienced physician.

When gross abnormalities were recognized, these were immediately referred to the attending physician. All Class III "Pap" smears were reported by the department of pathology to the attending physician, and he was requested to have a gynecologist see the patient in all cases.

Of the 3,840 patients interviewed, 1,668 had had a "Pap" smear done the year previous to admission. A total of 650 smears were actually done of which 422 were Class I, 221 were Class II, and 5 were Class III, and 2 were Class IV. Of those patients in whom a "Pap" smear was not done, 256 were too ill. In another 1,185 no order was obtained from the physician permitting the nurse to perform the test. Only 12 patients were not done because the physician objected. In 69 cases, the patient refused.

Of the 5 patients with Class III, 2 from a repeat "Pap" smear were reported as Class II. One patient left the hospital before a GYN consult could see her; and one had far advanced metastatic carcinoma of the breast in whom it was elected not to pursue the subject further because of her near terminal condition. One of the two patients with a Class IV smear was found on GYN examination to also have an ovarian carcinoma; she was explored and found to have metastases to the bowel and also to the pleural cavity for which she received chemotherapy. The other patient with Class IV smear was a 37-year-old registered nurse; mother of two, who was admitted to the psychiatric service. The "Pap" smear was reported as Class IV; biopsy showed epidermoid carcinoma-in-situ with one focus of

questionable microinvasion. A hysterectomy and left salpingo-oophorectomy were performed with the right tube and ovary left in place. The pathologist found one focus of residual carcinoma-in-situ on the specimen. The patient is now in excellent health.

It is interesting and ironic that in our initial discussions the feeling was that the psychiatric service should be excluded along with the intensive and coronary care units. In fact, early in the program the few physicians who objected to having a "Pap" smear done were mainly those on the psychiatric service. Following the case just outlined, there have been no refusals by physicians on the psychiatric service.

In the year just prior to the pilot program, October 1, 1970, through September 30, 1971, a total of 96 "Pap" smears were done on in-patients. In the year of the program from October 1, 1971, through September 30, 1972, there were 650 "Pap" smears done on in-patients.

There is obviously room for great improvement, but considerable progress has been made in the circumstances of a community hospital with limited resources. Following this successful experience, the hospital's Personnel Health Program instituted routine "Pap" smears for all female hospital personnel. Continuation of the routine "Pap" smear project as part of the routine admission work-up of the hospital admission was approved by the Administrator.

It has been difficult to pinpoint costs precisely. It was estimated that the procedure of taking a smear and giving the patient educational literature required about 10 to 12 minutes. Nurses were then being paid about \$5.16 per hour. "Pap" smears cost \$5.00 each in our laboratory (although some outside commercial laboratories were charging only \$3.00 each).

The hospital charged only the \$5.00 for the laboratory fee and nothing for the nurse's service in obtaining the smear. Thus, aside from defaults by third party payers or patients, the hospital incurred a loss of at least \$1.00 per "Pap" smear performed.

In view of the potential lives saved (5 so far), this was viewed as an acceptable contribution to community well-being and preventive health. The results of the three years since the pilot project have vindicated this investment in human life.

From October 1, 1971 to March 31, 1976, in the four and a half years so far evaluated, 14,992 patients were interviewed and 2,231 "Pap" smears done. Only 686 patients refused and only 12 were refused by their physician. For technical reasons, 2 could not be done; 730 were too sick to have the procedure; and 8,146 were done in the year previous to admission. Unfortunately, 1,185 women could not be examined because they were having other studies that conflicted, or an order was not received from the physician in time to perform the test before discharge. The distribution of reports on

smears were: Class I - 1,501; Class II - 712; Class III - 9; Class IV - 9. The followup on the 18 cases reported as Class III or IV yielded the total of 5 cases definitely positive of 2,231 smears done, a detection ratio of approximately 1:445. This is about the incidence generally reported for screening.²

Interestingly, the program stimulated office "Pap" smears, because the number of women who had the test performed in private offices increased with time. Plans for a screening program with an out-patient indigent group are being discussed. It is anticipated that the yield would be higher in such a population.³

The value of a routine nurse-run "Pap" smear program seems clear. It is recommended that every hospital explore the possibility for early detection of cancer of the cervix at a curable stage.

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New Developments in Screening for Genetic Disease

(This is the third of a series of six articles on genetics.)

Margretta Reed Seashore, M.D.

Genetic screening is receiving increasing attention throughout the world, and new methods are being developed for use in screening programs to detect or prevent genetic disease. Since genes cannot be identified or analyzed directly, screening methods are directed toward the products or results of mutant genes. Large numbers of individuals can be tested to identify those who are at risk for genetic disease. The screening approaches now in use can be divided into three classes:

- 1) Screening for diagnosis: to detect individuals already symptomatic.
- 2) Screening for presymptomatic detection: to discover individuals at risk for developing symptoms.
- 3) Screening for prediction of genetic risk: to identify individuals with genetic risks which require reproductive planning.

There are three important criteria which a good screening test must fulfill:

- 1) It must have no false negatives and few false positives.
- 2) It must be inexpensive.
- 3) It must utilize an easily obtained specimen.

Screening methods which fulfill all these criteria cannot be considered to be final diagnostic tests, but rather indicators for more definitive studies.

Screening for diagnosis may be illustrated by the following case:

A five-year-old white boy was being evaluated for developmental retardation. Birth history was unknown since the child had been adopted as a neonate. All milestones had been slow. The diagnosis of infantile autism was being considered because of hyperactive behavior and failure to relate to people. A urine screening test,

performed to look for evidence of an inborn error of metabolism, revealed the presence of phenylketones and phenylalanine. The diagnosis of phenylketonuria (PKU) was made using quantitative plasma phenylalanine determination.

Simple methods are in use to test urine and blood for the presence of abnormal metabolites or abnormal amounts of normal metabolites. Most methods utilize chromatography or electrophoresis, alone or combined, and ninhydrin stains for aminoacids (Figure 1). Rapid test tube reactions are also used to identify the presence of ketoacids, sulfur amino acids, phenylketones, mucopolysaccharides, and reducing substances. Such screening of the already symptomatic child should be considered in the evaluation of children with developmental retardation, unexplained acidosis, seizures, or growth failure. As with all screening tests, these do not stand alone as diagnostic tests; more quantitative and definitive studies are necessary. The nature of further tests depends on the disorder being sought. The patient with PKU illustrates the disadvantage of screening after the development of symptoms. In the case of PKU, by the time mental retardation has developed, the brain damage is so severe that dietary therapy is not effective. This need to detect many metabolic disorders early in order to treat effectively has stimulated the development of presymptomatic screening programs.

New born screening offers the most common example of presymptomatic screening designed to identify, before symptoms develop, individuals already affected with a disorder which requires treatment. The PKU program can be examined as a prototype of such programs. It is estimated that over 90% of the infants born in the United States today are screened for PKU. The first pilot studies in 1962 laid the

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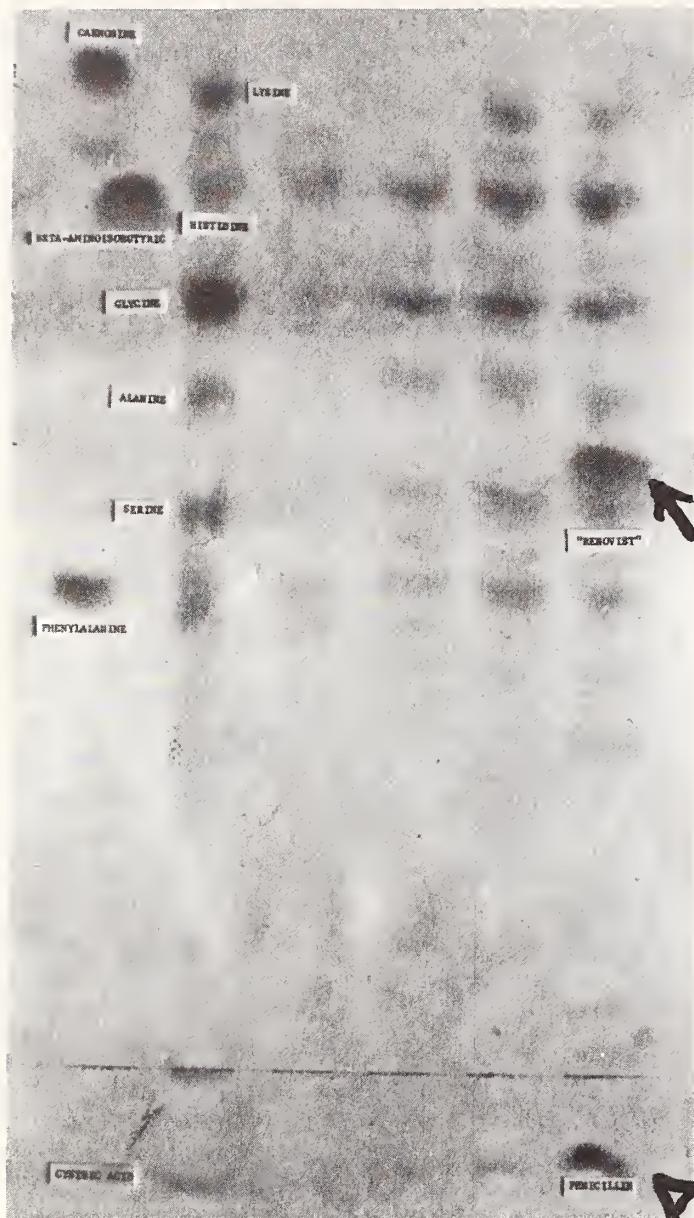


Figure 1

Electrophoretogram obtained by High Voltage Paper Electrophoresis in formic acid, pH 1.7 at 2.0 K.V. Note that the individual amino acids can be identified. The large ninhydrin stained spot (arrow) is Renovist, IVP dye. Ninhydrin stained spot behind the origin (arrowhead), is penicillin. Since such drug artifacts can make interpretation confusing, it is important to inform the laboratory of any drug the patient is receiving.

groundwork for PKU screening, thirty years after Folling's description of phenylpyruvic oligophrenia and eight years after the survey by Jervis establishing PKU as a cause of mental retardation.¹ The National Association for Retarded Children pressed for screening legislation in 1964, and in 1965 a Collaborative Study was begun to examine the factors necessary for success of the program. Much has been learned in the ensuing ten years. The evidence is heavily in favor of the effectiveness of the phenylalanine-restricted diet in preventing mental retardation. The amount of phenylalanine needed for growth has been ascertained, and dietary management of PKU is well es-

tablished. PKU screening has not been without its problems, however. Benign variants not requiring treatment have been recognized, and in the past some of those children were treated unnecessarily with the phenylalanine-restricted diet. Careful evaluation of the infant whose PKU screening test is positive is needed in order to differentiate benign hyperphenylalaninemia from true PKU. There is good preliminary evidence that stopping the diet at age six years is safe and successful.² Some problems remain, however. False *negative* tests for PKU, largely due to the timing of the tests, are now being recognized. Between 5% and 10% of children with PKU don't have a positive test for PKU if they are tested before the third or fourth day of life, because of variations in the rate of rise of blood phenylalanine concentration.^{1,2} With earlier discharge of neonates from the hospital, this is becoming a more and more serious problem.

The Connecticut PKU screening policy is of interest to all physicians who care for children in our state. The screening law was passed in 1965, and since then 30 children with PKU have been identified, an incidence of 1/15,000 births. A blood sample is obtained from the infant in the nursery just prior to discharge and sent to the State Health Department Laboratories in Hartford, where the Guthrie bacterial inhibition test is performed. A blood phenylalanine value of more than 4 mg/100 ml is considered abnormal, and demands evaluation by quantitative methodology. Because two infants later diagnosed to have classical PKU were missed by the Connecticut screening procedure, the Connecticut PKU screening program has recently been re-evaluated. One infant who was missed, was discharged from hospital prior to three days of age, and was not tested; the other had had a negative test age 80 hours when discharged. Both of these children are now mentally retarded. These children provided the stimulus to change the PKU testing procedure in Connecticut. The present recommendations state that all infants should have blood taken for PKU testing prior to discharge, regardless of age. Mothers whose babies are discharged prior to the fifth day of life should be told that the early test for PKU is not sufficient, and that a second test should be obtained at the clinic or physician's office. The ideal age for this second test is two weeks, and present recommendations suggest age two weeks as a good time for the first postnatal office visit and the second blood test for PKU. The urine test at age two weeks is no longer considered sufficient. Patients who need further evaluation of a positive Guthrie test can have definite testing in collaboration with the genetics services at University of Connecticut (Dr. Robert Greenstein, 674-2676) or at Yale (Dr. Y.E. Hsia, 436-3654).

The cost of such a massive screening program is obviously an important issue. Several estimates of the cost of PKU screening have been published.^{3,4} In New York, it costs about \$2.65 per test to screen for PKU, and about \$38,000 per confirmed case. Considering the cost in institutionalization of the untreated patient, a savings of \$50,000 per confirmed case is estimated. Levy⁴ has estimated the cost of the Massachusetts neonatal screening program, a program that includes testing for a number of other inborn errors of metabolism in addition to PKU. His figures describe a cost of \$15 per patient screened, including an office visit at age two weeks. The tests themselves cost about \$2.60 per neonate screened. The Massachusetts group estimates that the neonatal screening program has saved the state over \$300,000 annually. It must be recognized, of course, that these calculations ignore the fact that there are certain fixed costs of running institutions for the mentally retarded which would not entirely disappear if all the children with PKU were saved such institutionalization. So the calculations of cost-benefit ratios are not entirely representative of actual dollar savings at present. Nevertheless, the principle, if extended to include all recognized treatable causes of mental retardation becomes increasingly valid as more such situations are identified.

In addition to newborn screening for PKU, prenatal screening of pregnant women is being considered. Untreated maternal PKU is now recognized as a cause of microcephaly and mental retardation in the offspring, who are unaffected with PKU. Such screening could be of benefit because dietary therapy of the pregnant mother may be effective in preventing brain damage in the infant.

Other inborn errors of metabolism are being sought in neonates in addition to PKU. The Connecticut Health Department laboratory employs a spectrophotometric assay of galactose-1-phosphate uridyl transferase activity to screen for galactosemia. This condition is exceedingly rare, about 1/100,000 births, but it causes very severe illness (jaundice, liver failure, cataracts, retardation, and even death) and can be successfully treated with a galactose-free diet. As with all screening tests, false positive results can occur, and a definitive enzyme assay on fresh red blood cells must be done to confirm the diagnosis.

In Massachusetts, paper chromatography of blood and urine is used to screen for many inborn errors of amino acid metabolism and transport. Maple syrup urine disease, though rare, is very severe, treatable, and easily detected by these methods. Disorders reflected by abnormalities in glycine concentration can be detected, and many of these, such as some forms of propionicacidemia and methylmalonicaci-

demia which lead to unremitting acidosis and death, can be successfully treated. Tyrosinemia, which can be transient in prematures or evidence of a severe inborn error of metabolism, may be related to the development of intellectual deficits, and can be detected by these methods.

In addition to identifying infants in need of treatment prior to clinical illness, large-scale screening has also contributed to our understanding of the natural history of many disorders of amino acid homeostasis. It is through mass screening programs that the variants of PKU have been recognized and increasingly understood. Variations in amino acid metabolism which are not associated with disease have also been recognized. For example, histidinemia is not regularly associated with clinical abnormality and probably does not require treatment.

Priorities in establishing screening programs must be set. It is generally felt that those disorders which are known to cause clinical abnormalities and are amenable to treatment should be the subject of the major effort.

The overall incidence of inborn errors of amino acid metabolism and transport observed in Massachusetts by Levy⁵ was 1/2500 neonates; of these about 60% are clinically significant; Levy's methods also detect heterozygotes for cystinuria and prematures with transient tyrosinemia, and his incidence figures reflect this. The frequency of serious inborn errors of amino acid homeostasis has been determined by several surveys throughout the world,⁶ Table A. The variation among the different areas may be related to the genetic differences, sample size, or other factors. If Connecticut continues to have 35,000-45,000 births annually, 14-18 infants will be born each year with such an abnormality; of these infants, one-third will become mentally retarded if untreated. Some others may have serious disability; many will need further evaluation and genetic counseling. Since the cost of screening for PKU alone is about one-third the cost of institutional care of those patients, the case for such neonatal screening seems to be a strong one. It is obvious that the quality of life so preserved cannot be evaluated in financial terms. Arguments that screening might result in misdiagnosis and unnecessary treatment seem to be best met by safeguards in the procedures which follow an abnormal screening test, rather than by discontinuation of screening. Newborn screening offers the advantages of early ascertainment and treatment.

Infantile hypothyroidism is well established as a cause of mental retardation. Clinical diagnosis of this entity in the young infant is fraught with error, and early treatment is essential to successful preservation of intellectual function. Thus techniques to screen

Table A

<i>Disorder</i>	<i>No. Detected</i>	<i>No. Screened</i>	<i>Incidence</i>
Cystinuria	77	554,301	1:7,000
PKU (world).....	1186	13,538,912	1:11,500
Hyperphenylalaninemia (world)	133	13,538,912	1:30,000
Iminoglycinuria (world).....	28	554,301	1:20,000
Histidemia.....	41	1,001,193	1:24,000
Hartnup (world).....	21	55,301	1:26,000
Galactosemia.....			
Gal-I-P-U-T deficiency.....	41	3,099,738	1:75,000
Gal-kinase deficiency	2	3,099,738	1:750,000
Homocystinuria (Canada).....	1	77,913	1:77,913
Homocystinuria (U.S.).....	4	1,038,013	1:260,000
Homocystinuria (world).....	12	2,654,310	1:220,000
MSUD (world)	15	2,972,387	1:200,000
Tyrosinemia (Persistent)	1	1,401,777	1:1,401,777

newborns for abnormal thyroid function have been sought.⁷ Techniques using filter paper blood samples have been developed to assay T4 and TSH concentrations, using radioimmunoassay techniques. If thyroid function is absent or very low, the T4 (thyroxin) concentration in the blood will be abnormally low. If the pituitary axis is functioning normally, TSH (thyroid stimulating hormone) will be produced in excess, and this too can be measured. The combination in serum of a low thyroxin concentration and high TSH concentration strongly suggests congenital hypothyroidism, and definitive diagnostic studies are necessary. The T4 concentration may be low in patients with hypopituitarism who are not making TSH. In these infants, TSH concentration will be low. In addition, patients with low thyroid binding globulin concentrations (from prematurity, hereditary TBG deficiency, liver disease) or decreased TBG binding activity (from Dilantin displacement) will have low TSH concentrations but normal free thyroxin, not measured by the screening test. Therapy, of course, depends on the situation, and infants with normal free thyroxin do not require thyroid replacement therapy. The present recommendations call for a second filter paper specimen at age six weeks from infants whose T4 concentration is low and TSH is normal. It is of particular importance to recognize that thyroid disease is a dynamic process, and that the finding of a normal newborn screening test does not preclude the later development of hypothyroidism. The State Health Department recommends referral for evaluation of an abnormal thyroid screening test, to one of the two local centers which are part of the regional New England program: Yale Pediatric En-

docrinology Service (M. Genel, M.D., 432-4013) or Pediatric Endocrine Service, Newington Children's Hospital, a part of the University of Connecticut program (K. Arulanantham, M.D., 666-2461).

Screening for obtaining reproductive information involves identifying individuals whose genotypes imply a risk of having abnormal offspring. This kind of screening does not identify persons who themselves have a genetic disorder or who require treatment. Instead, the results of this kind of screening serve to identify persons heterozygous for genes which, if combined with an appropriate gene from a mate, would result in abnormalities in offspring. Most of this kind of screening is presently aimed at recessive, or "hidden" genes, which cause problems only when present in double dose.

The most successful heterozygote (carrier) screening programs to date have been those which have fulfilled these three criteria:

- 1) There is a specific, identifiable population group at risk.
- 2) There is an accurate, simple carrier test.
- 3) There are reproductive options available, such as prenatal diagnosis.

A pertinent example of heterozygote screening for reproductive information is Tay-Sachs carrier testing. Tay-Sachs disease (TSD) is a disorder of sphingolipid metabolism which results in storage of gangliosides in nerve cells, thus destroying the central nervous system and ending in severe brain damage and death. The ganglioside storage is a result of the absence of a degradative enzyme, Hexosaminidase A. Decreased activity of this enzyme in heterozygote carriers of the

gene, coupled with its predilection for Ashkenazi Jews, has made it possible to identify populations at risk and offer carrier screening.⁸ The Connecticut Tay-Sachs Disease Prevention Program has screened over 2000 people in the two years of the program's operation. The carrier frequency is about 1/30 among Ashkenazi Jews.

Thalassemia (Cooley's anemia), offers another example of a situation in which carrier screening can be effective. Patients who are homozygous for the gene for β -thalassemia have a microcytic, hypochromic anemia resulting from deficient hemoglobin synthesis. In the heterozygous state, characteristic changes in red cell size and in the proportion of the two hemoglobins, HgbA₂ and F, allow carrier identification.⁹ Since this gene has its greatest frequency in people whose ethnic origin is the area of the Mediterranean Sea, individuals of Greek and Italian extraction comprise the population at greatest risk. Pearson, O'Brien, and their colleagues have offered thalassemia screening in Connecticut, and have suggested a carrier frequency for β -thalassemia in Italian Americans of 2.5%, and in Greek-Americans of 5.0%. The new developments in the techniques available for prenatal diagnosis of β -thalassemia offer more reproductive options for families who are at risk.¹⁰

Sickle cell anemia is another example of a genetic disorder, recessively inherited, common to an identifiable segment of the population, in which the affected and heterozygote individuals can be easily identified. About 8% of the American black population are heterozygous carriers for the sickle gene, and about 1/500 black people have sickle cell anemia. Pearson and O'Brien have screened over 2500 newborns for homozygous sickle cell disease¹¹ and several thousand adolescents and adults for the heterozygous carrier state. Many individuals have also been screened at the Connecticut State Department of Health. It is most important, in doing sickle cell screening, that the distinction between the homozygous affected state and the carrier state be made very clear. The object of neonatal screening programs is to detect affected infants prior to the onset of symptoms in order to identify infants who may have a higher than usual risk of overwhelming infection and sickle cell crises. Although no specific therapy for sickle cell disease is presently available, awareness of affected infants can lead to prompt medical intervention in case of illness and result in lower morbidity and mortality. Heterozygous carrier screening, however, is appropriate for individuals who may be planning families, in order to identify those at risk for having children with sickle cell disease. There is little evidence that sickle cell trait has pathologic significance except perhaps for high altitude, hypoxic situations.¹²

The technical aspects of screening for sickle cell trait pose some difficulties, but methods which are reliable and feasible are in current use.⁶ An electrophoretic method using dried blood has recently been reported⁶ which may simplify the technical problems. The confusion in the public mind between "sickle cell disease" and "sickle cell trait" has caused no end of difficulty, and points up the importance of an extensive and thorough educational program prior to screening. The entity of "sickle cell non-disease" has appeared: children with sickle cell trait and without clinical illness have been subjected to restrictions in activity which have been wholly unwarranted.

Physicians who wish to refer patients for sickle cell or thalassemia screening may call Dr. Richard O'Brien at the Yale Department of Pediatrics, 436-8664.

Screening for heterozygous carriers of the sickle cell gene has stirred much controversy in this country. The predominance of this disorder in the American black population has intensified the problems indigenous to all carrier screening programs because of the racial strife this country has seen. The sickle cell situation serves to illustrate the ethical and social issues of such screening particularly well. The availability of techniques of screening for reproductive information has raised many methodologic, ethical, and social questions.

For heterozygote screening to be effective, the methods used must be accurate and reproducible, must utilize easily available tissue, such as urine or blood, and must be adaptable to efficient analysis of large numbers of specimens. Since it is unlikely ever to be practical to test the entire population for all known deleterious genes, target populations must be selected in which the gene frequency is sufficiently high to warrant the effort involved. The ethical and social issues that such population selection entails can be most troubling. They form the basis of the belief that screening programs for carrier identification should be undertaken only in response to community demands. Such community interest may be the result of educational programs which have been designed to inform without stimulating undue fear and anxiety. Those who meet with community groups in this capacity must be very well informed about the technical capabilities, genetic implications, and reproductive options available. There must be absolute assurance that all screening results will be confidential, and that participation is voluntary. Adequate genetic counseling must be available. Mass screening programs can be successful only if these stringent requirements are met.

It is crucial to the success of any screening program that the results not be misinterpreted. Screening tests are devised to handle large numbers of specimens using

inexpensive methodology. They are not meant to be definitive diagnostic tests. An abnormal result from a screening test should be considered as an indicator that further definitive diagnostic testing, using quantitative and specific methodology, be undertaken, and diagnosis must be certain before any therapy is begun. Care must be taken not to alarm families unduly, particularly in the case of newborn screening tests. These precautions cannot be overemphasized.

The effects of many genetic disorders are not yet preventable by the application of screening methods. Because of the lack of biochemical understanding of muscular dystrophy and cystic fibrosis, mass screening procedures to test for affected individuals and carriers in these conditions are not yet feasible. Since little is known about the efficacy of early therapy of the hyperlipidemias in preventing cardiovascular complications, screening to identify newborns affected with these disorders is not being done at this time, and carrier screening is not yet feasible.

The number of genetic and metabolic disorders which can be identified by simple screening methods is increasing (Table B). The demand for such services will increase as availability increases. The decrease in mortality from infectious disease has served to focus attention on the importance of genetic disorders as major causes of childhood and adult morbidity and mortality. The Hezekiah Beardsley Chapter of the American Academy of Pediatrics, recognizing the need for informed collaboration among physicians and health services throughout the State, has established a Committee on Screening, composed of members from pediatric practice, genetics and endocrinology services from both universities, and the State Health Department. Experience with PKU screening has taught us to be cautious with mandating screening by law, alert to

unrecognized genetic variants, cognizant of the need for follow-up, and respectful of the privacy of individuals. We have at hand the possibilities for many new opportunities to prevent the consequences of defective genes. We must use these means wisely, effectively, and for the benefit of future children.

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Table B
METABOLIC AND GENETIC DISORDERS IDENTIFIABLE BY SCREENING METHODS

<i>Disorder</i>	<i>Affected</i>	<i>Carrier</i>	<i>Routine in Newborn*</i>	<i>Available in Connecticut</i>
PKU	yes	no	yes	yes
Hypothyroidism	yes	no	yes	yes
Sickle cell anemia	yes	yes	no	yes
Thalassemia	yes	yes	no	yes
Tay-Sachs Disease	yes	yes	no	yes
Cystinuria	yes	yes	no	yes
Galactosemia	yes	no	yes	yes
Aminoacidopathies	yes	no	no	yes

*State Health Department

The Pathogenesis and Therapy of a Case of Malignant Hypercalcemia

Gregory R. Mundy, M.D.

Case Presentation

The patient was a seventy-year-old white male who presented to the Hematology Service in February 1975 with symptoms of exertional chest pain and epigastric discomfort accompanied by nausea and intermittent vomiting. Three months prior to admission a gastric ulcer had been diagnosed by gastroscopy at another hospital. Antacid therapy had not relieved the symptoms. At that hospitalization a total white cell count of 10,000 cells per mm³ with 20% atypical lymphocytes had been noted. A bone marrow examination revealed a number of lymphocytoid cells with similar morphology in the aspirate.

At the time of presentation at the University of Connecticut Health Center, physical examination revealed splenomegaly with a splenic margin palpable 7 cms below the left costal margin and an hepatic edge palpable 3 cms below the right costal margin (total span 14 cms). There was no lymphadenopathy. The hematocrit was 30% with a reticulocyte count of 2%. The total white cell count was 22,000 per mm³ with 35% immature lymphocytes and a platelet count of 100,000 per mm³. The patient's serum calcium was 6.8 mEq/L (13.6 mg/dl), with serum phosphorus 2.9 mg/dl, serum albumin 4.0 gm/dl, serum sodium 142 mEq/L, serum bicarbonate 31 mEq/L. The BUN was 45 mg/dl but fell with rehydration to 20 mg/dl. The serum PTH concentration was 74 uEq/ml (normal less than 90 uEq/ml) when the serum calcium was in the normal range. X-ray examination of the chest showed a right lower lobe infiltrate. A technetium diphosphonate bone scan revealed scattered increased uptake of the isotope in the skull and thoracic cage.

Initial treatment was by rehydration with normal saline. Salmon calcitonin was also given initially in a dose of 200 MRC units intramuscularly each 12 hours and the serum calcium fell dramatically from 6.8 mEq/L to 5.5 mEq/L over 36 hours. However, during the following 24 hours, the serum calcium gradually rose again back to pretreatment levels (7.0 mEq/L) and prednisone therapy was begun at a dose of 30 mgs each day. The serum calcium again fell within 12 hours to 4.5 mEq/L, where it was maintained throughout the remainder of the patient's hospital admission. The decrease in serum calcium was accompanied by improvement in the upper gastrointestinal symptoms of nausea and vomiting. The hypercalcemia responded to prednisone without any change in the circulating white cell count or the hepatosplenomegaly. A pleural biopsy taken from the area of the right lower lobe infiltrate showed infiltration of the pleura with lymphosarcoma cells. Chemotherapy was initiated one week later with a combination regimen of cyclophosphamide, vincristine and prednisone in a cyclical regimen every two weeks. A good response was obtained over the next two months with increasing hematocrit, decreasing size of the liver and spleen, and decrease in the total white cell count to normal levels although a few

abnormal cells persisted in the peripheral blood. The patient was then followed for the next 18 months as an outpatient on continued intermittent chemotherapy without any recurrence of the hypercalcemia.

Discussion of Case

A general review of the diagnosis and therapy of hypercalcemia was presented in Connecticut Medicine recently.¹ This discussion will be directed at the pathogenesis and treatment of malignant hypercalcemia with special reference to data obtained from studies on this patient with lymphosarcoma cell leukemia.

Pathogenesis of malignant hypercalcemia

Tumors involve the skeleton in a number of different ways. The most frequent is osteolytic bone resorption, which occurs most commonly in patients with carcinoma of the breast, lung, and kidney and also in hematologic neoplasms such as myeloma. More rarely, patients with malignant disease develop osteoblastic bone lesions where new bone formation is the major abnormality. This occurs most often in patients with carcinoma of the breast and of the prostate. Some patients with malignant disease become hypercalcemic but have no demonstrable metastases. The hypercalcemia is presumably due to release of a humoral mediator of bone resorption by the tumor cells. This circulating mediator causes bone resorption at sites distant from the tumor by stimulating osteoclasts. This category is being recognized more frequently as serum calciums are determined more often in patients with malignant disease.

Until recently, the pathogenesis of osteolytic bone lesions in malignant disease has been obscure. Now it is increasingly apparent that in many patients bone resorption is due to osteoclast stimulation by the tumor cells either locally or at a distance from the tumor. A number of human and animal tumors have now been shown to secrete humoral osteoclast stimulators. Another possible mechanism for bone resorption by malignant cells is a direct lytic effect of the tumor cell itself. Both of these mechanisms will now be discussed in more detail.

GREGORY R. MUNDY, M.D., Assistant Professor of Medicine, University of Connecticut School of Medicine.
Presented in Farmington on August 11, 1976.

1. Evidence for humoral mechanisms of bone resorption in neoplastic disease.

a. Osteoclast Activating Factor (OAF)

It is likely that OAF was responsible for the hypercalcemia which occurred in this patient with lymphosarcoma cell leukemia, and is also responsible for bone destruction in other patients with hematologic malignancies. Of the hematologic malignancies, myeloma is most frequently accompanied by osteolytic bone lesions and hypercalcemia, although malignant lymphomas occasionally present with skeletal disease as well. Osteoclastic bone resorption is frequently seen in Burkitt's lymphoma adjacent to the tumor cell deposits in the jaw.² It has been found that the cellular mechanism of bone resorption in these diseases is osteoclastic (Figure 1) and that the tumor cells secrete local factors which cause bone resorption by stimulating osteoclast activity.^{3,4} Malignant cells were obtained from the peripheral blood from this patient with lymphosarcoma cell leukemia. These cells were cultured and found to secrete a potent osteoclast activating factor *in vitro* with similar chemical and

biological characteristics to OAF produced by normal activated leukocytes.^{4,5} Cultured neoplastic cells from patients with chronic lymphocytic leukemia not associated with hypercalcemia or bone lesions do not produce bone resorbing activity when cultured *in vitro*.⁴

Normal osteoclast activating factor is released by stimulated human peripheral blood leukocytes activated by an antigen or mitogen such as phytohemagglutinin.⁶ Myeloma cells are neoplastic plasma cells which are in turn the progeny of B-lymphocytes. B-lymphocytes, plasma cells, and myeloma cells all secrete immunoglobulins. Therefore, it is reasonable to expect that a neoplastic myeloma cell could secrete other normal products in common with its ancestor, the B-lymphocyte. This is what we have now shown for the cultured neoplastic cells of this patient with lymphosarcoma cell leukemia⁵ and other patients with myeloma.⁴

Osteoclast activating factor produced by normal human peripheral blood leukocytes is a macromolecular protein which exists in at least two forms in

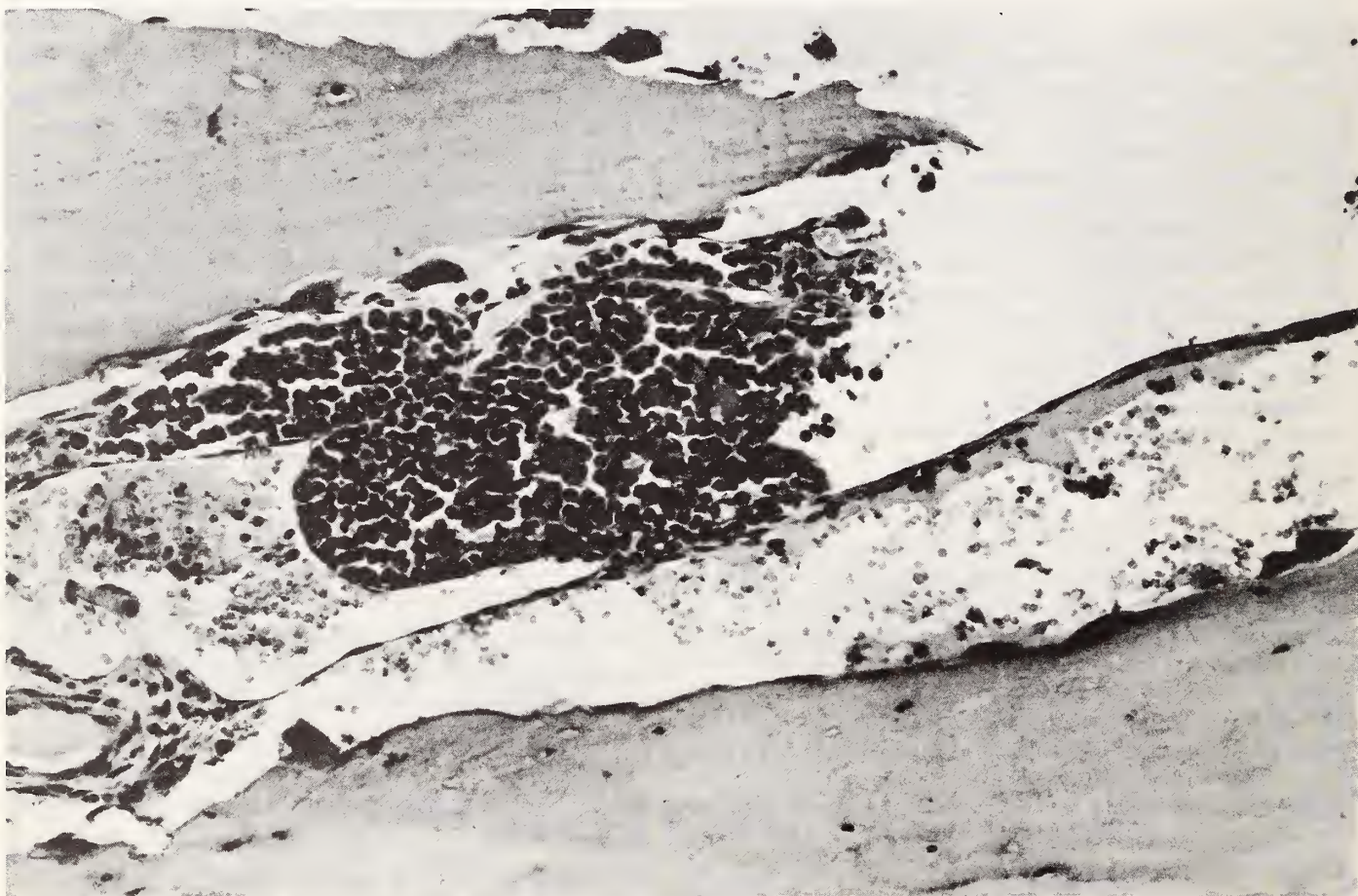


Figure 1

Histologic section of an osteolytic lesion from the clavicle of a patient with myeloma. The marrow myeloma cells are secreting an OAF-like factor which is stimulating osteoclasts on the adjacent endosteal bone surface to resorb bone. Corticosteroids reduce bone resorption by directly inhibiting osteoclasts. (Reprinted with permission of the New England Journal of Medicine).

leukocyte culture supernatants.⁷ The larger form is called Big OAF and elutes from Sephadex columns between the molecular weight markers chymotrypsinogen (25,000 daltons) and cytochrome C (12,500 daltons). The smaller material has been called Little OAF and can be obtained from Big OAF by dissociation in 1M NaCl or 2M urea, and may represent a subunit of the larger molecule.

b. Prostaglandins

Prostaglandins have been suggested recently as mediators of hypercalcemia in patients with malignant disease.⁸ These conclusions are based on the original observation of Klein and Raisz⁹ that prostaglandins-E stimulated bone resorption *in vitro*. This observation was followed by that of Tashjian *et al.*¹⁰ who showed that prostaglandins of the E series were responsible for hypercalcemia in a mouse fibrosarcoma tumor. These workers later extended this observation to the Walker rat carcinosarcoma.¹¹ No reliable data existed in humans except for occasional case reports based on measurements of increased circulating prostaglandin concentrations and responsiveness to indomethacin until Seyberth *et al.*¹² showed that PGE-metabolites were increased in the urine in a group of patients with malignant hypercalcemia. Indomethacin, which inhibits the synthesis of prostaglandins, reversed the increased excretion of prostaglandin metabolites and relieved the hypercalcemia in some of the patients.

To date, prostaglandins have been shown to be responsible for hypercalcemia in only a small number of situations. Moreover, there are several problems which need to be overcome before prostaglandins can be considered as a common cause of malignant hypercalcemia. Firstly, prostaglandins are local mediators of bone resorption and the prostaglandins which are known to stimulate bone resorption are inactivated in the circulation. Thus to ascribe malignant hypercalcemia without bone metastases to prostaglandins, it is necessary to show that stable metabolites of the prostaglandins both circulate and stimulate bone resorption. Secondly, indomethacin therapy, which blocks prostaglandin synthesis, rarely alleviates malignant hypercalcemia. It should also be remembered that prostaglandins as yet have been shown to cause bone resorption and hypercalcemia only in few animal tumors whose human counterparts are rarely seen in clinical practice.

c. Parathyroid hormone (PTH)

Albright first suggested in 1941¹⁴ that PTH may be secreted by tumor cells to produce a syndrome resembling hyperparathyroidism in the patient with malignant disease. This was a speculation arising from a discussion of a patient with carcinoma of the kidney and a solitary metastatic bone lesion in the ilium who developed hypercalcemia. It was suggested that bone

destruction from the osteolytic lesion was not sufficient to account for the hypercalcemia and Albright proposed that the tumor cells were releasing a PTH-like substance which was responsible. At the time Albright made this suggestion, no mediators of bone resorption other than PTH were known.

Over the last 20 years it has become apparent that this syndrome of malignant disease and hypercalcemia without metastatic bone disease is fairly common. The mediator of bone resorption is unknown in the majority of cases. It seems unlikely in reviewing the current evidence that PTH is responsible for more than a minority of cases, although there is considerable controversy on this point. One laboratory¹⁶ claims that PTH secreted ectopically is responsible for the hypercalcemia that occurs in the great majority of patients with malignant hypercalcemia. However, the PTH that these workers describe has different chemical characteristics to normal PTH and is present in low concentration in the serum of these patients. Other problems with this so-called ectopic PTH are that it has only minimal biological activity and is produced by 30% of all neoplasms, whether or not bone lesions or hypercalcemia exist. The most convincing data that PTH is not responsible for most of the hypercalcemia which occurs in cancer is that patients with malignant hypercalcemia usually do not have the other biochemical features of primary hyperparathyroidism which are due to the renal tubular effects of normal PTH. Features such as an elevated serum chloride, decreased serum bicarbonate, decreased serum phosphate and increased generation of nephrogenous cyclic AMP are used to differentiate patients with primary hyperparathyroidism from those with malignant hypercalcemia. This is a discrepancy which needs to be resolved before PTH can be held responsible for the hypercalcemia of cancer patients. Recently it was found by Powell *et al.*¹⁵ that a group of 11 patients with the syndrome of cancer and hypercalcemia without bone metastases had bone resorbing activity present in extracts of the tumor cells which did not cross-react with antisera directed against PTH. This is strong evidence that PTH is not a common cause of malignant hypercalcemia.

Much confusion in this area has arisen because of differences in interpreting radioimmunoassay results in malignant hypercalcemia and the criteria accepted for a diagnosis of ectopic hyperparathyroidism. There are now a plethora of case reports where serum PTH concentration as measured by radioimmunoassay is in the normal range and this is claimed to be evidence for inappropriate elevation of circulating PTH relative to increased serum calcium concentration. We believe that there is little scientific evidence for acceptance of

this interpretation at this time. It is not clear that any of the PTH radioimmunoassays are sufficiently sensitive to distinguish small differences in PTH concentrations which are low or within the normal range, or to enable one to determine whether these differences are related to ionized calcium concentrations in the serum. Moreover, a few patients with hypercalcemia that is clearly not due to PTH have been studied,¹² including this patient with lymphosarcoma cell leukemia. Some of these patients show low values of immunoreactive PTH but others (such as the patient described here) are in the normal range.

2. Evidence for Direct Cellular Effects

There is as yet no conclusive evidence that tumor cells can cause bone destruction by a direct effect on bone without the intervention of the normal major bone resorbing cell, the osteoclast. However, it is entirely possible that tumor cells can cause bone resorption by the release of enzymes which cause breakdown of the bone matrix and release of bone mineral. The enzymes which would most likely be involved in this process would be lysosomal enzymes. This type of resorption seems particularly likely in a disease such as breast cancer where hypercalcemia and metastatic bone disease often occur but patients rarely develop hypercalcemia without extensive bone metastases.

Treatment of Malignant Hypercalcemia

All patients with hypercalcemia should be treated with adequate rehydration. Further treatment of hypercalcemia is directed at the cause or underlying disease if this is possible. Malignant hypercalcemia is almost always due primarily to increased bone resorption. Therefore, medical therapy for this condition should be directed at decreasing bone resorption. There are four clinically available drugs which inhibit bone resorption. These are corticosteroids, neutral phosphate, calcitonin, and mithramycin. The use of neutral phosphate, calcitonin and mithramycin have been discussed previously.¹ In this particular patient corticosteroid therapy was strikingly effective. Other patients with malignant hypercalcemia sometimes respond to corticosteroid therapy, particularly if they have a hematologic malignancy or breast cancer. The mechanism of action of corticosteroid therapy in these situations has not been entirely clear. There are four ways in which corticosteroids could reduce hypercalcemia in this patient. Firstly, they could be reducing calcium absorption from the gastrointestinal tract. This seemed unlikely in this patient because his hypercalcemia responded rapidly to corticosteroid therapy at a time when he was not taking anything by mouth. Secondly, corticosteroids could be acting by a direct cytotoxic effect on the tumor cells. This also seemed unlikely in this patient with lymphosarcoma cell leukemia because there was a marked improvement

in the hypercalcemia before there was any change in the patient's circulating neoplastic cells or in the size of the liver or spleen. Thirdly, corticosteroids could have acted by a direct inhibitory effect on the synthesis or release of the bone resorbing factor by the tumor cells. Fourthly, corticosteroids could be inhibiting the action of the factor which stimulates osteoclastic bone resorption. This is a mechanism which was shown to be applicable to this patient. In this patient with lymphosarcoma cell leukemia and hypercalcemia the mode of action of corticosteroid therapy in reducing the hypercalcemia was studied by comparing inhibition of bone resorption *in vitro* with the patient's clinical response to therapy. When cell-free supernatant media taken from the patient's cultured tumor cells were added to cultured bone, bone resorption was stimulated; when steroids were added in small doses, osteoclastic bone resorption was totally inhibited.⁵

Using other methods, namely calcium kinetic studies and metabolic balance methods, others have shown that bone resorption may be inhibited by steroids in myeloma.^{17,18} However, these results do not define the mechanism of action of the steroids which could be inhibiting bone resorption as we have shown by a direct effect on bone or indirectly by acting on the tumor cells. Furthermore, these methods cannot assess changes in local bone resorption.

Calcitonin caused an initial rapid, but transient, reduction in the hypercalcemia in this patient. This drug may be useful in the emergency situation, but is unpredictable in the therapy of chronic hypercalcemia. It usually produces a response within several hours of administration which is not maintained after 24-72 hours.¹⁹ This patient demonstrated a typical calcitonin response.

The other drugs which inhibit bone resorption and their place in the therapy of hypercalcemia have been discussed fully in recent review articles.^{1,19}

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A Summary of AMA, Medical and Health News

A Section on Medical Schools was established by the House of Delegates at the AMA's 30th Clinical Convention in Philadelphia. Membership will consist of the dean of each approved medical school and three members of each administration or faculty who will be appointed by the dean. The Section on Medical Schools joins the Resident Physician Section and the Medical Student Business Session as special sections of the House closely allied to medical education.

A research project to identify the postgraduate education needs of physicians of various ages, specialties and practice settings and to determine how the AMA should respond to these needs was authorized by the Board of Trustees. Results of the study are expected for the 1977 Annual Convention. The Board also endorsed revised standards and criteria for the selection of convention sites.

AMA members could save as much as \$1,526 a year on their insurance plans according to a recent study conducted by William M. Mercer, Inc., insurance consultant to the AMA. The study compared individual insurance plans with the membership insurance program available through the AMA. The firm sought coverage from outside companies for a "hypothetical"

physician at age 46, then drew comparisons with AMA rates.

Resident physician sections have been established by the Houses of Delegates of the Washington State Medical Assn., the Illinois State Medical Society and the Texas Medical Assn. Six other state societies have formal resident physician sections and about 20 societies have some type of informal arrangement.

Physicians rank number one on the public scale of honesty and ethical standards according to a recent Gallup poll which asked a nationally representative sample of the public to rate the honesty and ethical standards of eleven occupations. Engineers and college professors ranked two and three respectively.

Medical group practice has shown significant growth in the 1970's according to the current edition of the AMA's Profile of Medical Practice. The information is compiled by the AMA's Center for Health Services Research and Development from the AMA's Physician Masterfile and the Periodic Survey of Physicians. The book shows there are 8,483 medical groups whose 66,842 physicians represent 23.5% of the active non-federal physician population.

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Designation of Primary Care Specialties

At its 1975 Spring Convention, the AMA House of Delegates referred "Designation of Primary Care Specialties" to the Council on Medical Service for study and report back at the 1976 December Convention.

With referral was a request that the Council consult with the various medical specialty societies concerned. Accordingly, it requested discussion and comment from the Interspecialty Council. In addition, a subsequent special communication to all Interspecialty Council Representatives and Alternate Representatives solicited additional comments on this subject. A separate letter was also sent to the organizations representing the four medical specialties named.

As a result, the Council on Medical Service has had, in addition to discussion at the Interspecialty Council meeting, the benefit of specific comments and/or presentations from the American Academy of Family Physicians, American Academy of Ophthalmology and Otolaryngology, American Academy of Orthopedic Surgeons, American Academy of Pediatrics, American Board of Family Practice, American Board of Internal Medicine, American College of Obstetricians and Gynecologists, American College of Physicians, American College of Surgeons, American Council of Otolaryngology, American Society of Internal Medicine, Association of Professors of Medicine, Federated Council for Internal Medicine, Section Council on Gastroenterology, and Section Council on Internal Medicine.

The definitions or descriptions of primary care suggested by many of the above organizations seem in general agreement on the three essential elements which comprise such care: (a) initial access to health services; (b) continuing patient centered responsibility for comprehensive care including prevention; and (c) coordination of other care resources needed by the patient. The report of the Citizens Commission on Graduate Medical Education in 1966 is also in essential accord with this definition of primary care, as is the Definition of the Role of a Primary Care Physician adopted by the House of Delegates in 1972.

That definition reads as follows:

"A physician assumes the role of a primary care physician when the patient depends on him for the initial access to and for the provision and overall management of his medical care. The same physician may not invariably continue in this role, but, by referral, another physician may assume it. In any specific health matter, the particular physician who accepts a patient for

primary care should assume continuing supervision of that care."

"This relationship may also be carried out by a group of physicians who function in a defined, responsible pattern of medical practice. In such a type of practice a single physician, however, should maintain an ongoing relationship with the patient and coordinate his care."

Considerable support was expressed in the comments to the Council for designating general and family practice, internal medicine, obstetrics and gynecology and pediatrics as "primary care specialties" in the light of this definition. Serious concern was also expressed, however, that direct patient access to physicians in other specialties not be precluded by incorporating such formal designations in legislation pertaining to the organization and delivery or financing of health care. It was pointed out that physicians in many other specialties may function in a primary care role for certain patients and during certain phases of their care episode.

The Council on Medical Service believes that the specialties of family practice, internal medicine, obstetrics and gynecology and pediatrics do constitute the major although certainly not the sole components of the profession which, together with general practice, provide this type of care for the public. At the same time, the Council fully concurs with the need to ensure continued direct access to physicians in other specialties.

The Council of Medical Service is also in sympathy with a resolution calling for inclusion of primary care training in the residencies for those specialties designated as "primary care." The statement on "The Continuum of Medical Education" adopted by the House of Delegates in 1970 (Council on Medical Education) requires the director of *any* unified program of graduate medical education to "insure that trainees in the program are adequately grounded in such of the broad fields of medicine, surgery, pediatrics, psychiatry, family practice and pathology as are appropriate to the program and to individual career goals" and further recommends that "all specialty boards requiring three or more years of graduate experience permit the substitution of at least one year of graduate education medicine, surgery, pediatrics or family practice for their own stated requirements." Subsequent statements approved by the House of Delegates, or by the specialty societies concerned, have given special encouragement to the inclusion of primary care experience in residencies for family practice, internal

medicine, obstetrics and gynecology and pediatrics. Based on the above considerations, the Council on Medical Service believes that the concerns of the various medical specialties involved would best be met by a substitute resolution to read as follows:

Resolved, That primary care is a type of medical care delivered by physicians which emphasize first contact care and assumes ongoing responsibility for the patient in both medical maintenance and therapy of illness; it is personal care involving a unique interaction and communication and includes the overall coordination of the care of the patient's health problems with the appropriate use of consultants and community resources; and be it further

Resolved, That the medical specialties of family practice, internal medicine, pediatrics and

obstetrics-gynecology be recognized as major, although not the sole, components of the profession which, together with general practice, provide primary medical care to the American public; and be it further

Resolved, That such recognition be in no way interpreted in legislation or otherwise as precluding the patient from having free choice of his personal physician or his consulting physician and also direct access to the physician he has so chosen; and be it further

Resolved, That training in primary care continue to be encouraged in all residency programs, and particularly in those specialties designated as major providers of primary care.

The above resolution was adopted by the House of Delegates, December 1976.

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The Physician as Sex Counselor

Edward Mason, M.D.

Abstract—The purpose of this article is to outline the changes that have taken place in sexual practices in the recent past. It points up the fact that physicians in the past have been poorly equipped to deal with their patients' sexual problems. It suggests a course of action to follow from medical school to clinical practice to alleviate this condition.

Even the most casual observer of life styles in the United States in the last quarter of the Twentieth Century would have to agree that attitudes towards human sexuality have undergone great changes. Graphic descriptions of sexual behavior abound in books and magazines in the bookstores of our cities. Sexual techniques and nudity stare back at us from the "silver screen." Furthermore, it is anticipated that soon, aside from a predesignated daily hour, we will "enjoy" the same excitement on television. Masters and Johnson have published two books and developed a classification of fornication whose wide general and scientific acceptance is further evidence of an increasing openness about sexual behavior.

Some of these changes have been sanctioned by recent Supreme Court decisions which have combined with other forces that have all contributed to the new attitudes. The influence of the wide-spread use of the birth control pill has to be considered a major factor. The "Pill" has allowed a generation of men and women to enjoy the pleasures of heterosexuality without the fear of pregnancy. The easier pursuit of sexual pleasure has also served to enhance society's interest in sexual practices.

The influence of the Women's Liberation movement has also played a role in bringing about a new openness. The modern woman will no longer tolerate a society where sex and its pleasures are discussed only by men at stag parties. Various women's groups have published material describing sexual organs, techniques and experiences. Today's woman will no longer accept a subordinate role to her man in the dissemination of sexual information nor will she accept less than equal sexual gratification.

The first sex researchers to receive wide general acceptance were Dr. Alfred Kinsey and his group. Later they were followed by Masters and Johnson who published the results of their studies. The books pub-

lished by Masters and Johnson appeared on the nation's best seller lists for many weeks. However, it was Sigmund Freud who first brought sexuality to the consciousness of the scientific community. He presented his findings to a hostile world which considered him a dirty old man. The temper of Freud's time was such that entire generations of men and women grew up without knowing the simplest facts of sexual anatomy and physiology. Unfortunately, the medical profession suffered from and perpetuated the same guilt-laden ignorance about sex as did the general community in the early Twentieth Century.

Nonetheless, it was not always thus. Sexual prohibitions and taboos were less blatant and in some primitive cultures sexual behavior was even more open than what we have seen happening in our own country in the last decade. Virginity was not always prized nor was nudity always discouraged. We could have learned a great deal from history and realized that sexual practices are never constant but are always changing.

One of the changes that has occurred is the marked increase in the use of graphic language describing sexual activity. Four letter words appear in books, magazines and are used in the movies. Pictorial nudity and the depiction of sexual intercourse and its variants are discussed and described more openly. Sex is here, everywhere around us; our patients are surrounded by stories of extramarital, premarital, nonmarital and homosexual sexuality. The generations are puzzled by each other's behavior. Some older folks have turned to the sex manuals and sex therapy clinics to assure themselves a place in the lineup of winners. The younger people seem to be under pressure to express their sexuality openly so they can take part in the machismo that accompanies the adulation that our youth culture appear to shower on sexual athletes of both sexes. In the meantime, some dishonest and pseudoscientific groups have risen to the demand and have established themselves as sex therapists—often promising much and delivering little.

What about the physician? For the most part, until very recently, he knew as little about sex as his neighbors. He knew the anatomy and physiology, the plumbing and the hydraulics but he knew little of the emotions involved. Too often the goal-oriented, obsessive-compulsive, controlled, disciplined, hard-working qualities that made good physicians were not very effective in helping to understand human sexuality. In addition, the training of the physician often emphasized the objective, the measurable rather than that which was subjective and emotional. Physicians, to deal

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with patients' sexuality, must recognize their own humanity and vulnerability.

In reality, there was no reason for the physician of the past to have been a good sex counselor. He knew the anatomy and physiology but not much more. As late as 1954, no American medical schools offered courses in human sexuality in their curricula; in 1973 the A.M.A. urged all medical schools and medical organizations to move towards providing formal education in human sexuality for all physicians at all levels. To be a counselor in human sexuality involves more than disseminating birth control information or devices. The physician must understand that human sexuality is a complex subject that involves emotions, religion, prejudices and the physician's own attitudes. Understanding the human sexual experience requires tenderness, patience, freedom from inhibition, preconceived bias and tolerance for our fellow men.

Sexual dysfunction brings patients to the physician with somatic complaints, marital unhappiness, anxiety, anorexia, insomnia and depression. The treatment of these problems must take place in the physician's office and not in the charlatan's show room. Up to this time, we physicians have failed to provide care for these problems. Our patients read Kinsey in the 1950s, Masters and Johnson in the 1960s and "The Joy of Sex," in the 1970s. Unfortunately, sex, like brain surgery, cannot be self-taught. Our patients will look to us for help; we must not fail them.

The future physician should begin his preparation to be a sex counselor even before entering medical school. In the past medical school admissions committees were much impressed with the premed student's achievements in the "hard" sciences. Perhaps they should look for more well rounded candidates. The student who has demonstrated in the classroom and in the community, his ability to relate to people and a sensitivity toward their problems can offer a great deal to his patients as a sex counselor. Students should be encouraged to study more of the humanities and social sciences so that they can know more about the world around them and the world that preceded them.

From the very first year of medical school, courses in human sexuality should be part of the curriculum. Many medical students today, even those of the "cool" generation, are still quite naive about sex. Sexuality should be discussed in small groups, not exceeding eight students and it is best done, of course, in sexually mixed groups. The discussion leader must be frank and comfortable with his or her own sexuality. A wide ranging three-hour seminar should include topics like attitudes towards the human body, premarital, extramarital and nonmarital sex, the development of the sex drive and an examination of the internal struggles all people experience during the sexual storm and stress of adolescence.

During the first year of medical school, discussion about sex might include a study of the sexual classics of our time—Masters and Johnson, *The "Joy Of Sex,"* and *"All You Wanted To Know About Sex,"* etc. These books may not rank with *"Gray's Anatomy,"* along the scientific spectrum but the medical student's future patients are reading them and a fledgling physician must know at least as much about his subject as his patients.

Another useful tool in teaching human sexuality is the use of films followed by small group discussions. It is beneficial to have the groups number six or eight and led by a mature couple who may or may not have a special relationship to one another. It is often beneficial for a medical student aged twenty-two to discuss films on human sexuality with a professor and spouse who may be twice his age. Both sides can learn a great deal and often the younger participant is amazed to discover that the "straight" "establishment" professor may really be "cooler" about sex than was expected.

The films that can be used in the course are varied. There is one that shows a medical couple performing a sexological exam on a supposedly sexually dysfunctional couple. The exam involves observation, palpation and inspection of the sexual parts of both partners. Perhaps, one of the most interesting parts of the film shows the male partner being examined in stirrups. Perhaps every future male physician could benefit from being examined while in stirrups.

The next film shows a couple having sexual intercourse. The act is performed by a young, healthy, vigorous, imaginative, uninhibited pair. They engage in foreplay with an exchange of tactile pleasures and proceed to a final genital experience. Oral-genital contact is shown with each partner participating and enjoying the total experience.

After the films are seen, small groups of students can be formed to discuss what they've seen. As the discussion progresses the students may find their voyeuristic pleasure can give way to clinical discussions of sexuality and that the sexual act can be discussed as easily and unashamedly as the respiratory act. This is truly the purpose of this educational exercise. The physician should learn as much about sexual functions as about the functioning of any other organs. Surely, there is nothing sinful about future physicians wanting to learn as much about sex as they need to help their troubled patients. The time has come for the medical profession to lead the way in clearing up the naivete about and ignorance of sexual functioning.

The training in human sexuality should continue beyond the classroom. The clinical clerk in medicine should be taught to listen for problems in sexual dysfunction that may account for abdominal pain, flank pain and headache. The clinical clerks in surgery and gynecology should be taught to consider

the role of sexual dysfunction in the etiology of dysmenorrhea and pelvic pain. In general, through the clinical years of medical school the student should be taught to listen for and take a sexual history, for every physician should remember that things are not always what they appear, and sexual problems may wear many disguises. A sexual history should always be included in any complete examination of every patient.

The question may arise as to the medical doctor's role in treating sexual dysfunction after anatomical and physiological pathology have been ruled out. Why not, at this point, make referral to a psychologist, social worker, marriage counselor or clergyman? If the referral has to be to a physician, why not let the psychiatrist handle the problem? However, the patient has made the choice. Despite other trends, most patients continue to seek out the family or primary care physician when their lives are disturbed or when they feel diseased. Primary trust in personal matters is still placed in the family physicians. Therefore, it is not a matter of choice, patients will continue to come to their doctor for assistance with sexual problems and especially if the problems are accompanied by somatic difficulties. As a profession, we must be prepared to deal with the problem or our patients may find their way to others less skilled and perhaps less honest. As a matter of fact, sex therapy charlatans have already begun to bilk the public with fancy titles and false promises. A compassionate physician, of any specialty, can, with a little thought and training, provide adequate sexual counseling. The physician should be aware of his own hang-ups and if he feels too inhibited, he should be aware of his own limitations and know which of his medical colleagues can take care of the problems. It is our responsibility as a profession to keep the patient out of the charlatan's show room.

The most common type of sexual dysfunction that may be seen could be called the syndrome of the well-meaning but inept couple. These are two people who, after varying degrees of sexual involvement, choose to make a permanent commitment to each other. However, despite previous experience the relationship fails. In the physician's office, both partners are apt to be embarrassed and question their own sexuality. The woman questions her femininity and the man his masculinity. They are puzzled and hurt by *their* mutual inability to make their sexual experience a gratifying one. They come to their family physician for help. What should the doctor do?

At this point, in a sufficiently large number of cases, no intense gynecological, psychiatric, or urological knowledge is required. The doctor should assume nothing, for even the most sophisticated and educated couples may have a reservoir of ignorance

about sexual anatomy. The physician should be able to provide counseling by use of words, pictures, charts and actual demonstrations. Is there anything sinful or deviant about showing the male partner where his wife's clitoris or vagina is, or teaching the female something about the scrotum, frenulum and glans of the penis? Shouldn't a physician, comfortable with his or her own sexuality, be able to teach a sexually troubled couple about the techniques of foreplay, kissing, breast fondling, genital stimulation and to relieve them of their guilt and anxiety about their urge to involve themselves in sexual techniques previously considered deviant and described only on latrine walls.

Some have assumed, incorrectly, that sex comes naturally. Fornication and deposition of sperm into vagina may be easy but the act of love is a complex matter involving all the senses, a lifetime of training and experience and expectations that may be beyond human capacity. A tired, down-trodden male makes a poor lover and an angry female makes for an unhappy experience. Love in an eight-cylinder bedroom, sexual intercourse undertaken with in-laws within earshot, are both usually doomed to failure. This may seem obvious to the experienced physician but to the young, frightened couple, it may come as a revelation that not every sexual encounter is a "home-run" or ends with a Boston Symphony Orchestra crescendo. The understanding physician can and should allay this anxiety with kindness and understanding. Most early sexual problems can be helped in this fashion and the family may be saved years of pain and misunderstanding by their physician.

However, the national interest in sex therapy has been directed generally towards the treatment of what some may consider more serious problems than simple sexual ignorance. The focus has been on more specific problems such as anorgasmic women, premature ejaculation in men, lack of sexual desire in both sexes, male impotency and vaginismus. For many years psychiatrists appeared to have a monopoly in treating these conditions. Sexual dysfunction was considered symptomatic of deep internal dynamic psychic turmoil. Treatment consisted of many hours of psychotherapy—unfortunately with very limited success. The psychiatrist's failure was replaced by the success of Masters and Johnson style of sex therapy.

Masters and Johnson provide treatment for patients and training for therapists that has brought relief from symptoms for thousands. Unfortunately, many of our patients cannot avail themselves of this type of treatment. In addition, many imitators and sex therapist entrepreneurs have arisen to bilk and cheat our patients. Therefore, we physicians must familiarize ourselves with some basic sex therapy techniques. We may do this to become therapists ourselves or to be more knowledg-

able about referring our patients to other therapists.

Masters and Johnson have demonstrated that the anorgastic woman, the premature ejaculating man and other sexually dysfunctional patients can be helped by an open approach to their problems. Both partners are involved in the treatment and are taught that the entire body is an erogenous receptor, non-demand sensory exchange with lovingly provocative stimulation is encouraged to help undue previously fearful, inhibited approaches.

The program may involve at least several sessions, sometimes in the presence of the therapist, in which the sexually dysfunctional couple are helped to come to know each other's needs and sexual desires. The details of the Masters and Johnson techniques have been modified by others and every physician should acquaint himself with their work and the writings of other legitimate sex therapists. Each physician can choose how much he wants to incorporate into his practice. Nonetheless, each physician should know enough at least to provide his patients with guidance in selecting a therapist if he does not choose to do this type of work himself.

A good physician can become uniquely suited by training and experience to be a sex counselor. The physician should start with a broad education in humanities in undergraduate school. In medical school, courses in anatomy, physiology, psychiatry, gynecology should be supplemented by curricula offerings in human sexuality to broaden knowledge and sensitivity. Later in clinical training and in practice the astute physician can learn to appreciate the suffering that sexual dysfunction can bring. Humanity can be brought to sex counseling by a humane physician who is prepared to treat his whole patient.

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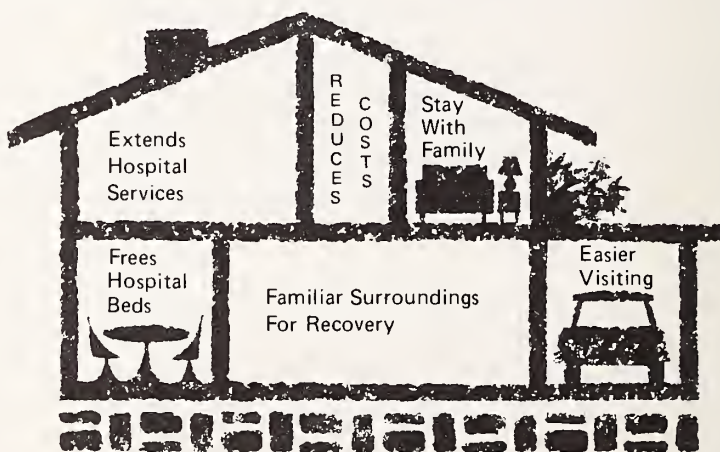
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Connecticut Hospitals and Health Commission

Commentary

Commission on Hospitals and Health Care

David A. Grendon, M.D.

Member, Commission on Hospitals and Health Care;
Chairman of the Council, CSMS

The problems of health care economics are most troublesome ones, for which simple solutions probably do not exist. As a political issue, health care has had an appeal which was recognized over a century ago by Bismarck, who used health insurance for political purposes. Health care in this country has taken on increasing importance over the last half century, with its greatest spurt due to the recognition of health as a natural right. As a corollary, it has become evident that health care is a bottomless pit into which we can pour literally unlimited sums. As the costs continued to mount, the need for underwriting them became obvious, either as insurance by Blue Cross or Blue Shield, by commercial insurers, or by prepaid group medical practice. While these third party payers served, for a time, to contain costs to the individual, they failed to solve the problem of costs to society, and we presently expend 8.6% of our gross national product on health, and are heading upward, with a prediction that the country would fall apart if we reached 20%.

As the costs escalated, with hospital costs rising at a rate three times as fast as the cost of living, it was only a question of time before legislation would be introduced, to make some control possible, as was done during the price freeze of the early 1970s.

In 1973 the General Assembly passed the law establishing the Connecticut Commission on Hospitals and Health Care, the function of which was to contain rising hospital costs. Parenthetically, there had been a voluntary Connecticut Hospital Planning Commission which had almost no power other than a requirement by the Connecticut Hospital Service that capital expenditures in excess of \$100,000 had to have prior approval by the Hospital Planning Commission. But after a period of about eight years, it became apparent that voluntarism in this area did not work, and the Commission on Hospitals and Health Care was established by law and given the power which a voluntary agency did not have.

For the first two years of its existence its relations with the hospitals were relatively amicable, because it did not, in fact, slow down the rate of climb in hospital costs. It was not until 1976 that the decisions of the Commission on Hospitals and Health Care had any significant effect on hospital budgets, and it was at this point that the cries of distress from hospitals

began to mount. And it is in response to these cries that the courts, the legislature and the assorted health providers are being solicited and mobilized, to reverse the trend of the past year. Many statements have been made which have little substance, and some have been complete distortions.

The fundamental fact is that hospital costs are rising at an unacceptably high rate, which may result in pricing hospital care out of the reach of the people, and which will likely result in a two-tier system of health care, one for the affluent and the other for those of limited means. It was to deal with this situation that the General Assembly acted in 1973. If the citizens of Connecticut, in their wisdom, decide that they are willing to pay whatever it costs to have a hospital system which someone chooses to call the best, this is society's prerogative. This is the manner in which our hospital system has always functioned, and were it not for the factor of rising costs, might continue to function.

Unfortunately, while the people want the best there is no incentive for them to consider the costs involved, since many of these are borne by third party payers, governmental or insurers. Cost control by itself would be a difficult enough problem to deal with, but if added to the equation we insert quality control and expanded access, we end up with an almost insoluble equation. Yet, in the real world, this is exactly the problem which confronts us. It was in response to this that the law establishing the Commission on Hospitals and Health Care was passed. And it was because the Commission on Hospitals and Health Care attempted to carry out its mandated duties that it is now attracting the wrath and vilification being heaped upon it by those who should know better.

The present climate is that having taken a step in the direction of cost control, let us hurriedly enact legislation to emasculate the Commission on Hospitals and Health Care. Since the simplest method of doing this would be to rescind the law passed in 1973, why is that not being proposed? For the very good reason that we would then revert to the status quo ante, a green light to the forces leading to uninhibited escalation of hospital costs. Since practically everyone involved pays lip service to the need for a regulatory agency to exert a controlling influence on the economics of the hospital industry, (which, off the record, many would rather not have), the obvious solution is to modify or amend the law so as to render innocuous any opinions or actions such a regulatory agency might develop.

Some of these proposed modifications are manifestly aimed at thwarting the legislature's goal of a preponderance of consumers on the Commission on Hospitals and Health Care, and a restriction of those whose interests are hospital industry oriented. One suggestion is so extreme as to design a commission under federal rather than state control, which is a denial of the customary position that the more remote, the more inflexible the control.

The argument that the Commission on Hospitals and Health Care should have a rate setting instead of a budget review function makes no sense, since the two functions are inseparable. Otherwise, rate-setting would be a simple exercise in arithmetic to be carried out by a bookkeeper.

And, finally, we have heard the turmoil created by the 'inflexible' guidelines used by the Commission on Hospitals and Health Care in its budget reviews. They can hardly have been inflexible since of the \$70 million originally cut, there was sufficient flexibility to permit restoration of \$44 million. There was, in fact, greater flexibility than in the preceding two years, but the outcry was occasioned by the impact which had previously been lacking.

In closing, there is no assurance that cost control in hospital economics is more than a small effort in the direction of dealing with a huge problem. It may not work, it may not achieve any great change, but it will have an effect on the rising costs of hospital care, and it will keep a modicum of local autonomy. The alternative is similar control from Washington.

The Larger Issues in Hospital Costs

Dorothy C. Goodwin, Ph. D.

State Representative from 54th District

The conflict between Connecticut's hospitals and the Connecticut Commission on Hospitals and Health Care (CHHC) over the 1976 budget review by the Commission raises some fundamental issues about the market for hospital care that are not well understood. In an effort to understand the nature of this very peculiar market, I have tried to identify some of the factors that keep this market from functioning as it should.

The results of this analysis follow. I present it knowing that I am a lay person in hospital administration matters, but I risk saying it even if it may be wrong, or incomplete, or out of focus, because I will be forced to face this issue in the current session of the General Assembly, and all of us there will need all of the help we can get from the experts on this problem.

So this is a plea for comment, criticism, suggestions and help from all of you.

Hospitals today seem to face irresistible forces leading to rises in costs that are on the whole even more rapid than the general rate of inflation. This does not appear always to have been true. Why should it be true now? At least six such forces, interacting with each other and reinforcing each other, seem to be major contributors.

a. The explosion in scientific discovery and medical technology. Medical schools, universities, private laboratories, for-profit health industries like pharmaceutical companies, research institutes, have all combined to give us a knowledge to provide a quality of health care undreamed of even 30 years ago. And every increment to knowledge uncovers a new area of imperfect knowledge to be explored. And so the drive continues.

We are not going to stop this scientific thrust, even if we starve its funding. The will to know is one that will not be denied, or even slowed for very long, once the tools of investigation are in place. It is too deep in our technological culture, too profoundly a part of the inner motivation of scientists, too responsive to the call of the suffering for relief and remedy.

b. The inner drive within the health professions for professional excellence. If the knowledge is there, doctors will use it. Doctors deal in human life and welfare, and most of them find that responsibility rather awesome. The drive for satisfaction in a job well done combines with a moral abhorrence of failure to meet responsibility, and together they force adoption of technology as it is developed. And so it should. No one would have it otherwise.

c. And the threat of malpractice suits means that no doctor dares to ignore new knowledge within his power to apply. The malpractice issue is too complex for full explanation here, but it has at least two roots that are relevant to this discussion. The absolute confidence of much of the public that doctors can produce cures if they will just try; and the general tendency of juries to make larger and larger awards in all kinds of negligence suits without regard to the longer range, more general consequences of these awards. The most crucial of these consequences is that large awards stimulate suits with ever larger claims.

d. The concept of health care as a basic human right. As our general standard of living rises, the notion that health care is a luxury for sale only to those who can afford it becomes increasingly unacceptable. And the objective of universally accessible health care can be largely achieved, with or without socialized medicine, through third party payments (Blue Cross, private insurance, Medicare, Medicaid), using mixtures of government subsidy and free enterprise insurance.

In a democracy as wealthy as ours, the drive towards accessible health care is not likely to go away. Nor should it. The justification for medicine for the elite alone is even harder to defend in a wealthy democracy than education for the elite alone.

e. The impact of third party payments. Before the days of third party payments, the effective restraint on hospital costs was the collective ability of patients to pay for services. In the absence of third party payments, that ability was severely limited. Services simply could not be mounted if their revenues, supplemented only by charitable contributions and endowment income, could not cover their costs. All this is changed now. We have third party payments, and this means that in the direct and critical sense that applies to individual bills, no one really cares how big the bill is. But we are no more likely to do away with third party payments than we are with scientific curiosity. They are an instrument of democracy, and no one who has access to them is likely to want to give them up.

f. The absence of a "bottom line." Unlike a business seeking to maximize profits by maximizing the difference between revenues and costs, there is no automatic internal check within the health delivery system.

A business must control costs by every possible device, and must set price so that the price level produces a volume of sales that will guarantee revenues in excess of costs. In the hospital setting, prices are set without regard to market demand forces, to cover costs, whatever they are. Third party payments guarantee revenues, at least up to a point, and the CHHC is the ultimate watchdog, but the point is that there are no internal downward pressures on costs.

Some analysts have identified wages paid to non-professional hospital staff as a major factor in cost increases. This is, of course, true. Our society has finally recognized its obligation to assure a reasonable standard of living to workers in this and similar classes. However, such wage increases have occurred across society, with a possible exception of migratory farm workers, and are not unique to hospitals. They would have occurred as part of a general trend in labor markets even if none of the forces identified above had been at work.

Any economic mechanism, from pricing to collective bargaining, works best and to the best net advantage of all parties if it works under enormous tension, so that opposing forces and interests cancel each other out at some at least temporarily optimum level that recognizes the needs of all. But the forces identified above combine to minimize, not maximize that necessary tension.

And so we have the CHHC, an outside regulatory force to insure that in the absence of tension within

the system, there is an inhibitor to rising hospital costs.

Such an outside force is as essential in health care now as it has been for generations in regulated monopoly utility industries. The principle is well established and in circumstances such as these, the unregulated market is not likely to re-emerge.

The question is not whether to regulate, but how.

The problem is that no one really knows how. The 1976 budget review was undertaken in too short a time frame, and with too little time for hospitals to use or react to guidelines submitted by the Commission *after* the proposed budgets had been constructed. The review involved a fairly complex formula that was not fully understood by the hospitals, and allegedly applied too rigidly by the Commission.

Formulas intelligently used can be helpful. They can force critical evaluation of divergences from formula values. They can serve as norms or as targets (not the same thing.) But they cannot, and they should not be allowed to substitute for judgment.

The extent to which the Commission did allow the formula to substitute for judgment is, of course, the crux of the hospital's court case. The hospitals quite clearly believe that its application was too rigid; the Commission as clearly believes that it allowed ample flexibility. And, it seems to me, the two parties are not really hearing, or listening to each other at the present time.

With a less telescoped budget review schedule, and with the added experience of one year, the problem should be easier in 1977. But it is important for both sides to begin to listen to each other. The problem is not going to go away and neither is regulation. We need to make a conscious decision on exactly where this tug of war will come to rest.

In the long run, the issue for society to determine is what proportion of Gross National Product we are willing to give to health services, knowing as we decide that every incremental unit allocated to health is drawn from other services or from general consumption.

With no effective ceiling on health costs generated from within the health service sector, one can conjure up a nightmare image of health gradually sucking a major portion of our substance unto itself.

There seems to be a growing consensus that rationing of health services may be the wave of the future. No more difficult bundle of moral choices could possibly confront the legislative process than that one. Yet virtually all of the foregoing discussion points in that direction.

It will take the wisdom of Solomon applied to the Sermon on the Mount to work our way out of this bind.

Input from both sides—indeed from all sides—will be required for solution. The fat is in the fire now, and for all its imperfections and weaknesses, the legislature cannot duck its duty here. We will need help, all the help we can get.

Dr. Goodwin is an economist and former director of Institutional Research at the University of Connecticut, now retired. She is also a corporator of both Hartford and Windham Hospitals.

Adapted from a letter to the editor of the Willimantic Daily Chronicle, published on October 19, 1976.

The Commission and the Statute

F. Bernard Forand

Executive Director, Commission on Hospitals and Health Care

I want to express my personal thanks to Dr. J. Alfred Fabro and the Connecticut State Medical Society for the opportunity to present the views of the Commission on Hospitals and Health Care regarding the fiscal 1977 hospital budget controversy. This public-spirited attitude of permitting all sides of the controversy to express their views is likely to lead to more informed opinion about one of the most critical issues now facing the American public: How much can we afford to spend for health care and who should make the decision as to where the health dollar is spent?

Since the structure and organization of the Commission was described in some depth in the February issue of *Connecticut Medicine*, I will only, by way of summary, state that the Commission is a consumer-dominated 15 member part-time body charged with the difficult task of assuring that the public receives high quality care at prices it can afford to pay. At the outset let me state that when the Commission was established by an act of the General Assembly in 1973, there was explicit recognition, founded on sound historical basis, that the Connecticut hospitals were either incapable of or unwilling to contain a perennial 14-15 percent annual inflation of their budgets. The experience since the Commission was created, has confirmed this finding emphatically.

However, for two years immediately following the creation of the Commission, it looked as if the partnership between the Commission and the hospitals envisioned by the legislature, was mitigating significantly the cost spiral in hospitals. During the first two years of budget review the Commission concentrated entirely on reviewing increases in charges to patients, and it appeared that these charges were being held to levels considerably below the national average. For example, in fiscal 1975 the increase was only 8.3 percent, rising to 9.6 percent in fiscal 1976.

Charge increases alone, however, do not accurately reflect the cost to the public for hospital services. This

fact became glaringly obvious during 1975 and 1976 when Connecticut Blue Cross filed 15 to 25 percent annual rate increases with the State Insurance Commission. How could Blue Cross need such large premium increases if hospital charges were going up less than 10 percent?

The answer came in the spring of 1976 after hospitals had filed their audited statements for fiscal 1975. The fiscal 1975 audits revealed that the patient revenues from hospitals—a much better barometer than charges paid by the public for hospital services—increased 15.8 percent. In addition, a startling fact emerged—the hospitals had generated \$17 million in excess revenue which they had neither requested nor been authorized by the Commission to generate. Preliminary findings of fiscal 1976 data showed that another 15-16 percent increase was likely, again well in excess of the charge increases approved by the Commission.

An analysis of the data showed that, while hospital admissions and patient days had increased only slightly, the volume of ancillary or special services increased dramatically. This phenomenon demonstrated that patients had received significantly more special services than patients treated in previous years.

The Commission received no evidence to justify either that this proliferation of special services was necessary, or that it had resulted in better care. Nor did it appear that the increased trend toward defensive medicine engendered by the malpractice crisis could account for such a large volume increase. On the contrary, it became evident that the major factor accounting for such large increases in ancillary services was a built-in incentive to the reimbursement mechanism which permitted hospitals to generate “profits” or more appropriately “surpluses” from their excess revenues. Rather than use these surpluses to offset the cost of patient care, hospitals used them to expand hospital services beyond levels authorized by the Commission.

It became obvious to the Commission that it needed to make major changes in its budget review mechanism to close the volume loophole and bring hospital revenue increases down from the 15 percent annual increments experienced during the first two years of the Commission’s existence.

If the Commission did not take prompt and drastic action, hospital care would soon be priced out of reach of the majority of Connecticut consumers. Consider that hospital revenues had almost quintupled between 1965 and 1976—rising from \$152 million to almost \$700 million. For fiscal 1977, hospitals filed budgetary increases of 16.9 percent or \$116 million in new monies. Implementation of these budget requests

would drive the cost of a day in a Connecticut hospital over \$200—a rate well in excess of the national average. Further, and even more disturbing, continuation of the 15-16 percent rate of increase experienced by Connecticut hospitals in recent years could drive the hospital costs in the state to \$500 per day by 1983 and an almost unbelievable \$1000 per day in 1988. The present comprehensive Blue Cross package which costs \$1000 per family per year could reach \$5000 per family for similar coverage by 1988 if the current rate of hospital inflation continues. This data convinced the Commission that it had to act decisively and speedily to stem this double-digit hospital inflation.

After several weeks of intensive interaction between the staff and members of the Commission, the Commission adopted a new budget review system which had several basic features. Firstly, it abandoned the old charge review system and substituted a new mechanism to review total patient revenue—a more sensitive indicator of what the public spends for health care. Secondly, it included a mechanism to remove the (existing) incentive for hospitals to produce surpluses by generating excess volume. It is important to note that this mechanism did not in any way limit the number of tests or procedures a hospital could perform but rather limited reimbursement to the variable costs of generating the excess volume. This so-called “neutral” position on volume neither rewards nor penalizes hospitals for excess volume. A third feature evaluated hospital requests for non-volume increases based on comparisons with other institutions.

As previously noted, the 35 voluntary hospitals in the state submitted budgets aggregating \$116 million over the \$686 million authorized for fiscal 1976. The resultant 16.9 percent increases compared with an increase in the state budget for fiscal 1977 of approximately 7 percent and an increase in the budgets of cities and towns in which hospitals are located of 6 to 7 percent.

After its initial review of these budgets, the Commission approved \$50 million in new funds or a 7.4 percent increase. All the hospitals contested the initial Commission decisions, and were given the opportunity to appeal these decisions in two public hearings. Based upon the information presented at these hearings, the Commission added \$22 million in additional revenues for a total of \$72 million or a 10.5 percent increase over the amount authorized in the previous year. It is important to note that, for fiscal 1977, larger budgets were authorized for each hospital in the state. Nevertheless, thirty-one of the 35 hospitals found the final level of increase granted by the Commission insufficient and have appealed to the courts.

The Commission remains committed to the concept that the people of Connecticut should receive high

quality care at prices they can afford. Recognizing that this presupposes a balance between our aspirations and what is financially bearable, the Commission will continue to strive, in cooperation with other accountable health care organizations, to realize this admittedly difficult objective. This includes improving productivity in hospitals, eliminating waste and duplication, encouraging more regional and statewide health planning activities, applying cost/benefit analyses to all requests for new and expanded services and promoting new and effective alternatives for delivering health care.

The Commission looks forward to this new challenge and, in cooperation with the Health Systems Agencies, the new Statewide Health Coordinating Council, the P.S.R.O.s and other stewards of the health care system, is confident that the challenge can be met successfully.

Connecticut Hospitals Seek Repair of Commission Legislation

Fred Hyde

Vice President and General Counsel,
The Connecticut Hospital Association

Connecticut hospitals are approaching the General Assembly this year, seeking to repair what they perceive as important problems with the manner in which the Commission on Hospitals and Health Care has functioned.

Since its inception, the Commission has approved hospital budgets for three fiscal years. Connecticut's hospitals, which have had operating deficits every year since 1972, had \$3 million in revenue removed from their operating budgets by the Commission in the summer of 1974, and \$8 million removed in the summer of 1975.

By the time the budget review process took place in 1976, new faces, especially a new Executive Director from Rhode Island, were working to change the basic process involved in the budget review. Rather than the program, personnel and supplies review which the Commission had conducted in 1974 and 1975, the new Executive Director, working through an ad hoc committee which did not meet in public, had decided to review hospital budgets by formula. The formulas used involved the application of a number of theories current in the literature of health economics, transformed into a regulatory tool. A so-called “unit cost screen” formula, for example, compared the expenses involved in delivering services at Yale-New Haven and Hartford hospitals with the expenses involved in delivering the same category of services at Connecticut's smallest general hospitals. Hospitals which deviated from the median unit cost were penalized, notwithstanding variations in case mix

(it costs more to treat sicker patients!) between hospitals.

Other formulas operated in a similar fashion: that is, an attempt to make all hospitals wear the same sized shoe, whether or not it fit.

The net result was elimination of \$44 million from the hospital budgets, an amount five times greater than that removed the previous year, and more than ten times greater than the analogous exercise in 1974. Immediately following the Commission's final decision, 31 of the 35 hospitals brought suit, and obtained a stay order which essentially allows them to implement their budget as originally planned, prior to any Commission review, but holds them at risk for refund of dollars which the court ultimately finds they did not deserve.

Strong reaction to the Commission's capricious activity has come from many individual legislators and from some members in the leadership of the General Assembly. In response, the hospitals have put together a proposal to limit the powers of the Commission, hoping to do so in a fashion which allows the Commission to continue to operate as a rate setting body, but forces it to take into account the deliberations of the Professional Standards Review Organizations and of the Health Systems Agencies.

The hospital proposal involves changes in the Commission membership and staff. With regard to the members of the Commission who are consumers, the bill proposes that the consumers be chosen from the Health Systems Agencies, so that at least they will have to report back to somebody concerning their rationale for Commission decisions. With regard to the staff, the bill proposes that the Executive Director, a key person in the regulation of health, mental health, nursing home and other agencies spending more than a billion dollars a year in Connecticut, at least have some training and some years of experience in administration.

With regard to the tools the Commission uses in its activity, a second bill proposes that the Commission must take into account various factors affecting a community, including the necessary expenses of health care institutions, the quality of service they provide, any duplication of service which may exist and be unnecessary, the cost of teaching and research programs, and income necessary to offset money-losing community service programs.

With regard to certificate of need authority, the bill proposes that this authority be transferred to the Statewide Health Coordinating Council, which at least will have some discernible interest in the availability of health services in different parts of the state.

With regard to the Commission's budget approval power, the bill proposes it be changed to a rate ap-

proval power. Further, the bill would authorize the Professional Standards Review Organizations to assist the Commission in determining the appropriateness of hospital projections for increased volume of services. Currently, the Commission is essentially usurping PSRO decisions, deciding what quantity of health and mental health services will be provided to the people of Connecticut by their physicians. Connecticut is the only state in the nation that has a regulatory agency with budget approval power. The equivalent would be authority of a Public Utilities Commission to decide how much electricity or water will be sold.

Finally, the bill provides that appeals from the Commission's decisions will be made through arbitration, with a panel of arbitrators consisting of one appointed by an aggrieved institution, one by the Commission, and one retired judge of the Superior Court, to be appointed by the Chief Justice of the State Supreme Court. Arbitration is seen as providing a quick, less expensive and more precise form of appeal. Not one of the cases brought by the hospitals in late September has yet come to trial, largely because of foot-dragging on the part of the defendant. The considerable expense involved in bringing such suits, although minuscule compared to the number of dollars at stake in health services, is especially galling to administrators attempting to manage the complex institutions which hospitals have become with less than adequate resources.

No easy answer exists for the problem of controlling the cost of hospital care. Many efforts are being made simultaneously through the PSROs for control of utilization; through P.L. 93-641 for control of capital expenditures; through state level regulatory agencies for control of rates; and through many other avenues, as well. Connecticut's budget review agency has demonstrated the understandable frustration of consumers in attempting to find quick and easy answers during the budget review process—just give the hospitals less money to spend. The simple answer to hospital costs, in fact, is not to provide services; the trick is to continue to meet the many service demands placed on hospitals at the same time that meaningful cost control efforts are implemented.

The ultimate target in the activities of the Commission, as is recognized by many leaders in Connecticut's medical profession, is the discretion given to the individual practicing physician in dealing with the problems of his or her patient in the hospital. Revenue control—the budget approval process—is aimed at what the Commission believes are unnecessary admissions, unnecessary ancillary services, and unnecessary surgery.

If you think you and your colleagues are fundamentally practicing good care in hospitals, then this is also your fight. If you think this fight is going to be won without your personal support and activity, you are wrong.

Letters To The Editor

Letters to the Editor are welcomed and will be published, if found suitable, as space permits. Like other material submitted for publication, they must be typewritten *double spaced* (including references), must not exceed 1½ pages in length and will be subject to editing and possible abridgment.

COMMENT ON BICENTENNIAL ISSUE

To the Editor: What a great issue of *Connecticut Medicine*! I had to send you a note about the December Bicentennial Number, with my congratulations on a beautiful piece of work. Everything—from the typeface on the cover, the editorial, the articles selected, and the various miscellaneous selections you inserted, show that you are a master of the subject.

I just recently completed reading Daniel Boorstin's trilogy on "The Americans." In Volume I his section on "New World Medicine" gave me the background to appreciate the depth of your accomplishment.

Keep it up! This represents a whole new visage for *Connecticut Medicine*, and although unfortunately it may be slow to be appreciated, it is a refreshing change. The December Issue ranks with the caliber of the *New England Journal* or *Lancet*.

Once again, my congratulations.

Bridgeport, CT

Robert W. Berry, M.D.

To the Editor: Thanks very much for the splendid Bicentennial issue of *Connecticut Medicine*. I am delighted to have it and am already reading it. You should be very proud of this publication. Among other things, I particularly like the careful scholarship that is evident in the issue.

Professor of Anatomy
Yale University School of Medicine

Thomas R. Forbes, Ph. D.

To the Editor: I thought you put together an excellent Bicentennial issue of *Connecticut Medicine* which I will keep in my file.

New Haven, CT

Howard M. Spiro, M.D.

To the Editor: My sincerest congratulations to you and your staff on the outstanding quality of your December Bicentennial issue. For clarity and completeness, yet for succinctness, this surpasses any other paper on the history of medicine in our country that I have seen.

Dr. Gert Wallach's treatise is indeed a work of art and his and Dr. James Tait Goodrich's two lists of references truly show the

extensive work they have put into their projects. As chairman of our Litchfield County Medical Association's Bicentennial celebration 10 years ago, I recall with great admiration and respect Dr. Wallach's papers on the colonial doctors of our part of the state.

Your quotes of the physicians' writings of 200 years ago gives an excellent insight into their activities and their daily lives. It was not only fun but enlightening to take the 19th century licensure quiz, and to see if our answers might have passed the Board of Examiners of that time. Of special interest too was "The Medical Log of Old Ironsides" by Dr. H. Benjamin Bradburn.

Thank you very much for bringing us such a wonderful issue at the close of our Bicentennial Year. It shows the great men who have gone before us in medicine in Connecticut, and should give us great challenge for the next centenary. If we have any doubts about the future conquest of cancer, heart disease, psychoses, etc., we need but remind ourselves of how our forefathers must have felt 100 years ago about the treatment of infectious diseases when they knew so little about bacteria, much less about physiology and biochemistry of the body cell and of our immune systems.

Sharon, CT

G.S. Gudernatch, M.D.

To the Editor: Your recent Bicentennial issue was admirable in concept. However, I find it incongruous that a state medical journal should publish two articles that contain 123 and 139 references respectively (see "The Mind of the Colonial Physician" and "The Colonial American Medical Student: 1750-1776").

I would think that such a pretentious display of scholarship would be better displayed in a graduate school journal of medical history.

The two prodigious lists of references of the articles in question occupied a space of four pages which you could have filled with material of more timely interest to your readers.

I would remind you of the words of Daniel Mason "The ideal of independence requires resistance to the herd spirit now so widespread, to our worship of quantity and indifference to quality. . . ."

Bethel, CT

Edward J. Volpintesta, M.D.

To the Editor: Does the journal regularly put out such excellent issues—or is this a Bicentennial exception? If the journal consistently has such high quality, I suspect I had better stop being a national chauvinist and pay more attention to what is going on at home.

Alvan R. Feinstein, M.D.

Professor of Medicine and Epidemiology
Yale University School of Medicine

To the Editor: Congratulations on a thoroughly enjoyable and extremely well done Bicentennial issue of *Connecticut Medicine*.

I am sure that you, Dr. Nuland and many others labored considerably over this fine product, to bring to our attention the achievements and follies of the past. I know for certain that my own education did not prepare me to take key parts of the 1899 examination of the Connecticut State Medical Society, including description of the therapeutic uses of cold, and the ability to write a prescription in latin unabbreviated. One other element that seems to have been missing was grave robbing, but then who knows . . .

Fred Hyde

Vice President and General Counsel
Connecticut Hospital Association

To the Editor: Thank you very much for sending me a copy of the "Bicentennial Issue" of *Connecticut Medicine*. It is an elegant interesting work for which you and your colleagues merit high praise.

I have gone through the book hurriedly and will return to it for more thorough study. Among other items that caught my eye was the 19th century licensing examination. I wonder if you or I could write answers that would satisfy the 1899 Examining Committee.

Best wishes for 1977.

Former Editor of *JAMA*

Hugh H. Hussey, M.D.

To the Editor: Your labors as guest editor are apparent throughout the issue and I especially enjoyed your introduction; to find also among the contributors one or more friends and former associates was likewise the source of real pleasure. I thought that Brad's handling of the Old Ironsides log was splendid.

I have always believed most deeply that the true physician shared a place among educated persons. The interest and enthusiasm of some of us for the history of our guild is I hope one of the characteristics that qualifies us as "educated".

With deep gratitude and, as always, with all my best.

Wardsboro, Vermont

Courtney C. Bishop, M.D.

To the Editor: I have just read the December issue of the Journal and have revelled in its wonderful contents. It is surely a fine job and I congratulate Dr. Nuland, the Guest Editor, and you on it.

Stanley B. Weld, M.D.
Editor Emeritus

West Hartford, CT

To the Editor: I want to congratulate Dr. Nuland on a superb and exciting issue. I hope this venture into our cultural past and our medical history will be enjoyed as enthusiastically by physicians in Connecticut and elsewhere as much as it deserves. The issue was an interesting diversion from our regular format and was composed with thoughtfulness, taste and wit.

The scholarly treatise by Mr. Goodrich is most rewarding reading and it had the special merit of sending me all the way through the 3rd and 2nd Editions of Webster's Unabridged to the Unabridged Oxford English Dictionary to find "minimifidianistic."

Seriously, though, the caliber of articles was high and the issue will stand as a valuable memento of our Bicentennial year.

Putnam, CT

John L. Meyer II, M.D.

To the Editor: Your Bicentennial Issue is a positive banquet!

John G. Freymann, M.D.

President,
National Fund for Medical Education
Hartford, CT

The Editor emphasizes that all credit for the Bicentennial Issue goes to the Guest Editor, Dr. Sherwin B. Nuland.

PENTAZOCINE (TALWIN)—A CONTROLLED SUBSTANCE?

To the Editor: The article by Drs. Adriani and Naraghi in *Clinical Use of Narcotics* in Volume 40, No. 11, pages 745-750, November, 1976 contains an error on page 746 which should be corrected. In describing the different chemical groups into which narcotics are classified by derivation, the authors mention "the mild narcotic pentazocine (Talwin)."

Pentazocine is not currently listed as a controlled substance under the Controlled Substances Act (PL 91-513), nor is it classified as a narcotic according to the description of the 1974 amendment to the Controlled Substances Act. Furthermore, the Food and Drug Administration Controlled Substances Advisory Committee has reviewed information on pentazocine and has recommended to the FDA that pentazocine not be classified as a controlled substance.

Pentazocine is a member of the benzazocine series, and it is a potent analgesic which in appropriate doses weakly antagonizes the analgesic effects of morphine, meperidine, and phenazocine. If anything, pentazocine is in a class by itself.

Harold A. Burnham, M.D.

Associate Medical Director
Winthrop Laboratories
New York, NY

The above letter was referred to the author of the article in question, who offers the following reply:

To the Editor: The article by Drs. Adriani and Naraghi entitled the *Clinical Use of Narcotics* which appeared in Volume 40, No. 11, pages 745-50 November 1976 does not contain an error on page 746 as alleged by Dr. Harold A. Burnham, Associate Medical Director of Winthrop Laboratories, manufacturers of the drug. Therefore, no correction is indicated as he requests. Pentazocine (Talwin) is chemically allied to phenazocine which is a member of the benzomorphan series. Various texts support this fact but we will quote from one—AMA Drug Evaluations, 2nd Edition, 1973, page 258.

"Pentazocine is an analgesic of the benzomorphan series; it is also a weak narcotic antagonist. Thus, it has pharmacologic properties of both agonists of the morphine type and of antagonists of the nalorphine type."

Thus, if it possesses agonistic effects of the morphine type drug it must be considered to have narcotic properties. On the same page, the statement appears "On the basis of controlled addiction studies and in clinical experience the dependence liability of pentazocine appears to be no greater than that of codeine; thus it is not subject to narcotic controls under the Comprehensive Drug Abuse Prevention and Control Act of 1970." Codeine is classed as a narcotic and is subject to regulations of the Controlled Substances Act.

The Controlled Substances Act lists substances, many of which are not narcotics, such as barbiturates, amphetamines, psychosedatives, etc. Substances that can from a pharmacologic standpoint, as for example pentazocine, be classed as narcotics are not necessarily subject to the Controlled Substances Act. Nowhere in the article do we mention that pentazocine is a controlled substance. The modification in the molecular structure of phenazocine whereby the methyl group is replaced by a dimethyl allyl group reduces its analgesic potency and "attenuates" it so that it possesses minimal or no addiction liability. It must be noted also that there have been instances of abuse of pentazocine by drug dependent persons.

Nowhere in the article do we imply that pentazocine is not a useful drug and a satisfactory analgesic. I personally conducted clinical trials with pentazocine when it was an investigative drug prior to approval of its New Drug Application.

Propoxyphene (Darvon) which is chemically allied to methadone presents a situation parallel to pentazocine. For many years it has been regarded as a "non-narcotic analgesic." It also possesses a minimal degree of dependence liability; but now this has been shown to be of sufficient degree to have it placed under the scope of the Controlled Substances Act.

It is our feeling that Dr. Burnham is making a "mountain out of a molehill" and is over-reacting to differences of the interpretation of the term "narcotic." Furthermore, our article does not deal with pentazocine but is concerned entirely with the use of "strong narcotic analgesics."

John Adriani, M.D.

Professor of Pharmacology, Louisiana State University School of Medicine and Consultant in Anesthesia and Pharmacology, Louisiana Health and Human Resources Administration.

New Orleans, Louisiana

MAMMOGRAPHY

To the Editor: Your November, 1976 issue of *Connecticut Medicine* contained a statement by the Cancer Coordinating Committee of the Connecticut State Medical Society which I find frightening. I am referring to the statement recommending that every negative mammograph report carry with it a statement that a negative report does not exclude malignancy.

If this procedure is carried to its logical conclusion, then every negative chest X-ray, G.I. series, etc., should carry the same legend. If a clinician does not realize that a negative mammograph or other negative lab test does not rule out the presence of malignancy, he should not be allowed to order that test. I am surprised that a distinguished body such as the Cancer Coordinating Committee would have allowed itself to have been misguided to this extent to recommend such an overly defensive practice.

I think that all members of the Connecticut State Medical Society should write Dr. Bradley, the Chairman of the Committee, urging rapid rescinding of this recommendation.

Bernard S. Shapiro, M.D.

New Haven, CT

The above letter was referred to the author of the article in question who offers the following reply:

"Everybody wants to have a hand in the great discovery. All I will do is to give you a hint or two as to names. The state should come I think, to be called anaesthesia. This signifies insensibility more particularly . . . to objects of touch . . . I would have a name pretty soon, and consult some accomplished scholar . . . before fixing upon the names which will be repeated by the tongues of every civilized race of mankind."

—*Oliver Wendell Holmes, November 21, 1846 in a letter to William Morton following his successful demonstration of ether inhalation for surgery at the Massachusetts General Hospital.*

To the Editor: Thank you for your interest in the Cancer Coordinating Committee's statement on mammography. Number one, it is gratifying to know that you read it. Number two, if every doctor in the state read it, the Committee would have accomplished its purpose.

You are perfectly correct when you say that no one should order a mammogram who does not realize its potential shortcomings. Unfortunately this is not what happens. It was for precisely this reason that the Cancer Coordinating Committee felt that a statement should be made to protect both the physician and the patient. You as a surgeon are very fortunate if all of the physicians in your area refer every suspicious breast to a surgeon, either without mammography or in spite of a negative mammograph. This has not been the case in various parts of the State. I personally have had three cases of breast cancer which were allowed to go untreated for six months or more because of the false sense of security created by a negative mammograph. Such delays are obviously a great hazard to the patient.

From the physician's point of view, being responsible for such a delay would create a considerable liability. Therefore if the radiologist can remind each referring physician that a negative mammography report does not exclude malignancy, a few malpractice cases may be eliminated. I do not think this will be necessary forever, but I do believe, and so do the other members of our Committee believe, that this Statement is a very worthwhile contribution to the physicians and the patients of Connecticut at this time when mammography is relatively new, its techniques changing and its significance not universally understood.

I will bring your comments before the Cancer Coordinating Committee at its next meeting but I feel reasonably sure that in view of the extensive consideration which has already been given to the matter the Committee is unlikely to "rescind its recommendation."

E. Tremain Bradley, M.D.

*Chairman, Cancer Coordinating Committee
Connecticut State Medical Society
Norwalk, CT.*

Month in Washington

Four key lawmakers, representing both political parties, have introduced into the new Congress an American Medical Association proposal for national health insurance.

Association President Richard E. Palmer, M.D. urged the 95th Congress and the Carter Administration to consider carefully "this forthright approach to national health insurance. This bill would extend health insurance to every American to a cost the nation could afford. It is a viable solution to the problem of providing quality health and medical care to everyone."

The Comprehensive Health Care Insurance Act of 1977 was introduced into the Senate by Senator Clifford P. Hansen (R-Wyo.) and in the House by Reps. Tim Lee Carter (R-Ky.), John M. Murphy (D-N.Y.), and John J. Duncan (R-Tenn.)

The medical profession's NHI plan would build on the structure of the present system of employer-employee group health insurance plans, mandating each employer to provide comprehensive and catastrophic benefit coverage with the employer picking up at least 65 percent of the cost. Employees would not be compelled to participate.

The self-employed as well as the non-employed could purchase qualified private health insurance, through pools if needed, at a cost not more than 125 percent of the cost of group plans. They would have all or part of the premium paid for by the federal government depending upon their income tax liability.

Small businesses that found the mandated plan an added financial burden would receive federal assistance.

Medicare beneficiaries could purchase supplemental insurance to bring Medicare benefits to a par with those offered elsewhere, with the government assisting people with limited resources. Medicaid would, for the most part, be supplanted under the program.

After a certain level of co-insurance was reached, depending upon income, insurance would cover all remaining expenses as a complete protection against catastrophic costs.

The co-insurance factor would deprive no one of needed care. The absolute maximum that any individual would have to pay would be \$1,500; the absolute maximum for any family would be \$2,000 in any given year.

Senator Hansen, a member of the Senate Finance Committee, said:

"The bill we are introducing today would solve the problem of financing for every American. It would guarantee quality medical care to everybody. It would cover the cost of catastrophic illness. It would be fully comprehensive in terms of benefits. It would build on our present system, rather than dismantling it and replacing it from scratch with a new one requiring the creation of a giant bureaucracy. It would allow everyone to choose his or her own physician, dentist and health insurance plan. And it would be a plan we can afford.

"This legislation would cover the poor by paying all of their insurance premiums. Those better able to afford to pay those premiums would be assisted in a fashion commensurate to their need by lesser degrees of government help. The affluent would even be encouraged to buy health insurance by a tax subsidy of ten percent of the premium cost.

"As the principal (Senate) sponsor, I am confident that this measure can meet our needs at a cost, in new dollars, that will not be burdensome," the Senator from Wyoming said.

Rep. Carter, ranking minority member of the House Health Subcommittee, said that "—as a member of the House Subcommittee on Health and Environment for twelve years, I have devoted much of my legislative effort to issues concerning our country's health care system. And as a physician, I have made a personal commitment to do what I can to help improve the health care of our people.

"As a co-sponsor of the Comprehensive Health Care Insurance Act of 1977 I believe this measure offers a workable approach to extending health insurance to every American. In large measure, this proposal retains the expertise and experience of our existing private health care sector in both its administration and financing.

"It is these proven skills and resources of the private sector which I believe we should build upon in developing a national health insurance program, and which should be supplemented only when necessary by government.

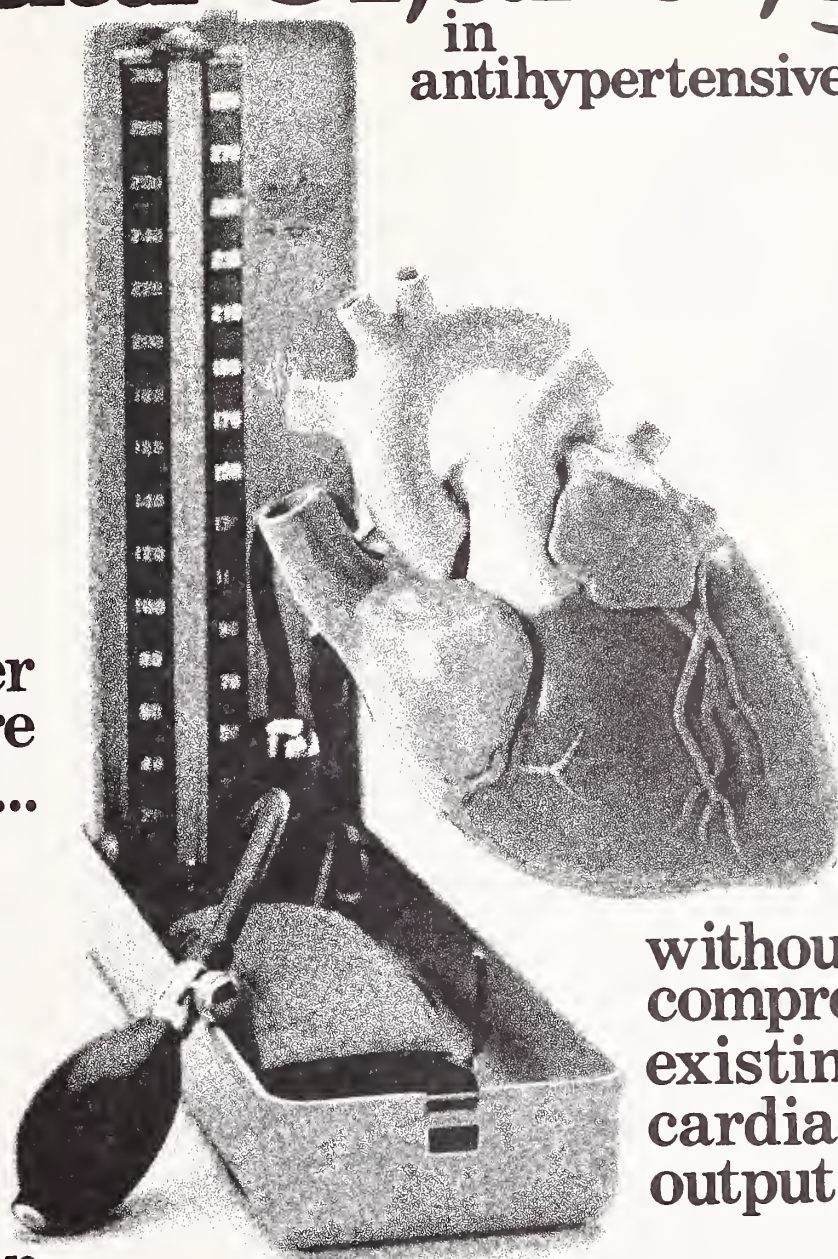
"This proposal would provide coverage to the great bulk of the American population through employer-employee financial arrangements in which not less than 65 percent of the premium would be paid by the employer," Carter said.

"For those who are self-employed or unemployed, health insurance would be provided through an income-tax credit or federal certificate of entitlement system. Thus this plan would correct one of the major weaknesses of our present system by removing the financial barriers that in the past have denied some

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For a brief summary of prescribing information, please see following page.

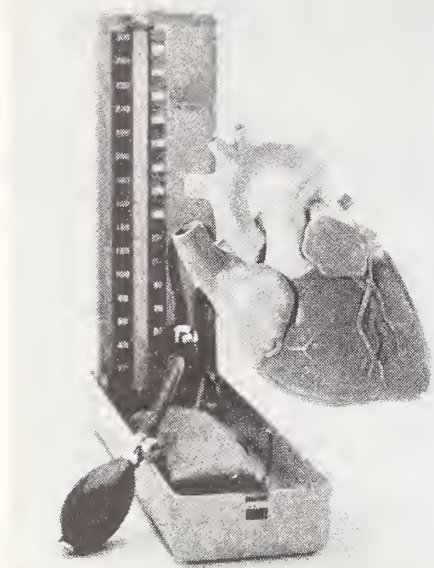
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effectively...
usually with no
direct effect on
cardiac function—
cardiac output is
usually maintained



Contraindications: Active hepatic disease, such as acute hepatitis and active cirrhosis; if previous methyldopa therapy has been associated with liver disorders (see Warnings); hypersensitivity.

Warnings: It is important to recognize that a positive Coombs test, hemolytic anemia, and liver disorders may occur with methyldopa therapy. The rare occurrences of hemolytic anemia or liver disorders could lead to potentially fatal complications unless properly recognized and managed. Read this section carefully to understand these reactions.

With prolonged methyldopa therapy, 10% to 20% of patients develop a positive direct Coombs test, usually between 6 and 12 months of therapy. Lowest incidence is at daily dosage of 1 g or less. This on rare occasions may be associated with hemolytic anemia, which could lead to potentially fatal complications. One cannot predict which patients with a positive direct Coombs test may develop hemolytic anemia. Prior existence or development of a positive direct Coombs test is not in itself a contraindication to use of methyldopa. If a positive Coombs test develops during methyldopa therapy, determine whether hemolytic anemia exists and whether the positive Coombs test may be a problem. For example, in addition to a positive direct Coombs test there is less often a positive indirect Coombs test which may interfere with cross matching of blood.

At the start of methyldopa therapy, it is desirable to do a blood count (hematocrit, hemoglobin, or red cell count) for a baseline or to establish whether there is anemia. Periodic blood counts should be done during therapy to detect hemolytic anemia. It may be useful to do a direct Coombs test before therapy and at 6 and 12 months after the start of therapy. If Coombs-positive hemolytic anemia occurs, the cause may be methyldopa and the drug should be discontinued. Usually the anemia remits promptly. If not, corticosteroids may be given and other causes of anemia should be considered. If the hemolytic anemia is related to methyldopa, the drug should not be reinstituted. When methyldopa causes Coombs positivity alone or with hemolytic anemia, the red cell is usually coated with gamma globulin of the IgG (gamma G) class only. The positive Coombs test may not revert to normal until weeks to months after methyldopa is stopped.

Should the need for transfusion arise in a patient receiving methyldopa, both a direct and an indirect Coombs test should be performed on his blood. In the absence of hemolytic anemia, usually only the direct Coombs test will be positive. A positive direct Coombs test alone will not interfere with typing or

cross matching. If the indirect Coombs test is also positive, problems may arise in the major cross match and the assistance of a hematologist or transfusion expert will be needed.

Fever has occurred within first 3 weeks of therapy, sometimes with eosinophilia or abnormalities in liver function tests, such as serum alkaline phosphatase, serum transaminases (SGOT, SGPT), bilirubin, cephalin cholesterol flocculation, prothrombin time, and bromsulphalein retention. Jaundice, with or without fever, may occur, with onset usually in the first 2 to 3 months of therapy. In some patients the findings are consistent with those of cholestasis. Rarely fatal hepatic necrosis has been reported. These hepatic changes may represent hypersensitivity reactions; periodic determination of hepatic function should be done particularly during the first 6 to 12 weeks of therapy or whenever an unexplained fever occurs. If fever and abnormalities in liver function tests or jaundice appear, stop therapy with methyldopa. If caused by methyldopa, the temperature and abnormalities in liver function characteristically have reverted to normal when the drug was discontinued. Methyldopa should not be reinstituted in such patients.

Rarely, a reversible reduction of the white blood cell count with primary effect on granulocytes has been seen. Reversible thrombocytopenia has occurred rarely. When used with other antihypertensive drugs, potentiation of antihypertensive effect may occur. Patients should be followed carefully to detect side reactions or unusual manifestations of drug idiosyncrasy.

Use in Pregnancy: Use of any drug in women who are or may become pregnant requires that anticipated benefits be weighed against possible risks; possibility of fetal injury can not be excluded.

Precautions: Should be used with caution in patients with history of previous liver disease or dysfunction (see Warnings). May interfere with measurement of: uric acid by the phosphotungstate method, creatinine by the alkaline picrate method, and SGOT by colorimetric methods. Since methyldopa causes fluorescence in urine samples at the same wavelengths as catecholamines, falsely high levels of urinary catecholamines may be reported. This will interfere with the diagnosis of pheochromocytoma. It is important to recognize this phenomenon before a patient with a possible pheochromocytoma is subjected to surgery. Methyldopa is not recommended for patients with pheochromocytoma. Urine exposed to air after voiding may darken because of breakdown of methyldopa or its metabolites.

Stop drug if involuntary choreoathetotic movements occur in patients with severe bilateral cerebrovascular disease. Patients may require reduced doses of anesthetics; hypotension occurring during anesthesia usually can be controlled with vasopressors. Hypertension has recurred after dialysis in patients on methyldopa because the drug is removed by this procedure.

Adverse Reactions: *Central nervous system:* Sedation, headache, asthenia or weakness, usually early and transient; dizziness, lightheadedness, symptoms of cerebrovascular insufficiency, paresthesias, parkinsonism, Bell's palsy, decreased mental acuity, involuntary choreoathetotic movements; psychic disturbances, including nightmares and reversible mild psychoses or depression.

Cardiovascular: Bradycardia, aggravation of angina pectoris. Orthostatic hypotension (decrease daily dosage). Edema (and weight gain) usually relieved by use of a diuretic. (Discontinue methyldopa if edema progresses or signs of heart failure appear.)

Gastrointestinal: Nausea, vomiting, distention, constipation, flatus, diarrhea, mild dryness of mouth, sore or "black" tongue, pancreatitis, sialadenitis.

Hepatic: Abnormal liver function tests, jaundice, liver disorders.

Hematologic: Positive Coombs test, hemolytic anemia. Leukopenia, granulocytopenia, thrombocytopenia.

Allergic: Drug-related fever, myocarditis.

Other: Nasal stuffiness, rise in BUN, breast enlargement, gynecomastia, lactation, impotence, decreased libido, dermatologic reactions including eczema and lichenoid eruptions, mild arthralgia, myalgia.

Note: Initial adult dosage should be limited to 500 mg daily when given with antihypertensives other than thiazides. Tolerance may occur, usually between second and third month of therapy; increased dosage or adding a thiazide frequently restores effective control. Patients with impaired renal function may respond to smaller doses. Syncope in older patients may be related to increased sensitivity and advanced arteriosclerotic vascular disease; this may be avoided by lower doses.

How Supplied: Tablets, containing 125 mg methyldopa each, in bottles of 100; Tablets, containing 250 mg methyldopa each, in single-unit packages of 100 and bottles of 100 and 1000; Tablets, containing 500 mg methyldopa each, in single-unit packages of 100 and bottles of 100.

For more detailed information, consult your MSD representative or see full prescribing information. Merck Sharp & Dohme, Division of Merck & Co., Inc., West Point, Pa. 19486

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Americans access to high quality care.”

Rep. Murphy, with Carter a member of the House Interstate and Foreign Commerce Committee, said the proposed legislation would provide “—more comprehensive benefits than any other (proposal) previously considered by Congress; and it would deliver quality health care to everyone—including the poor, and the elderly—without bankrupting the nation.

“For those unemployed, or of low or fixed income, and the elderly, premium costs would be paid by the government on an equitable sliding scale,” Mr. Murphy said.

“By building the private sector and helping those who need help the most, this approach avoids many of the problems inherent in other proposals before the Congress.

“Further, it would avoid additional burdens on an already beleaguered social security system, the preservation of which must be one of our highest national priorities,” according to Mr. Murphy.

Rep. Duncan, a member of the House Ways and Means Committee, questioning how Congress could write a national health insurance plan while preserving at the same time the fiscal integrity of the Treasury, said in prepared remarks:

“The Comprehensive Health Care Insurance Act of 1977 . . . controls costs by limiting federal help to those in need by determining that level of need from income tax liability. Additional cost controls are found in its co-insurance factor, except for the poor; its provision of preventive care; and its promotion of competition among health insurance carriers.”

* * *

The Carter Administration has announced through its new Secretary of Health, Education and Welfare that a “well-thought through” national health insurance proposal cannot be submitted to the Congress this year.

Joseph Califano, at his first press conference after confirmation as HEW Secretary, predicted that the Administration would first concentrate on health care cost controls and better utilization of existing federal programs.

The new HEW Secretary said the crucial appointment of an Assistant HEW Secretary for Health probably would not be made for a week or 10 days. He stressed the importance of such appointments, saying his choices could be the most important decisions he makes, since they will affect the source of HEW operations over the next four years.

Asked about reorganization of the HEW Department and the campaign proposal to make education a cabinet department, Califano predicted there would be no major reorganization proposal for his department that would be ready for submission to Congress this year.

He said he intends to “end politicization” of the National Institutes of Health, especially on the advisory committees, but did not go into any detail.

The major announcement at the conference was a comprehensive study of welfare reform bringing in all areas of government and the private sector for consultation. Califano said it is clear there is national support for an income security system, but that the public also is “impatient with the inability of our government to remove from the welfare rolls those persons improperly on them.” He foresaw a “great national debate” on the issue.

Asked whether groups such as the American Medical Association and the Pharmaceutical Manufacturers Association groups with interest in the Medicaid side of welfare would be consulted, Califano said they will be consulted as well as all other groups involved in welfare programs.

* * *

Medicare and Medicaid spending next fiscal year is predicted to top \$35 billion, up more than \$5 billion for the estimate of the current fiscal year. The Ford Administration’s final, and somewhat academic, budget proposal to Congress for financing the federal government next fiscal year set overall health, education and welfare spending in fiscal 1978 at \$159 billion, an increase of \$11 billion. More than \$100 billion of this, however, is in Social Security Trust Fund outlays.

There was little new in the budget plans for health compared with last year’s budget except for the steady creep upward (19 percent) of costs for Medicare and Medicaid. Budget requests for most HEW health activities were kept to about this year’s level. The Carter Administration is slated to submit its own federal spending plans about mid-February. These are certain to include hefty proposed boosts in some health areas.

HEW spending on health has jumped from \$9.7 billion in 1968 to a predicted \$42.2 billion. It will rise another \$3 billion next, year, according to budget charts.

* * *

Tightening Medicare-Medicaid fraud provisions is one of the first orders of business before Congress. Legislation has been introduced in House and Senate by key health lawmakers who pledged speedy action.

The bill, sponsored by Sen. Herman Talmadge (D-Ga.) and Reps. Paul Rogers (D-Fla.) and Dan Rostenkowski (D-Ill.), makes provider fraud a felony rather than a misdemeanor, arms Professional Standards Review Organizations (PSROs) with power to review “Medicaid Mills”, requires certain financial disclosures by non-physician providers; and requires PSRO to turn over information to state and federal agencies investigating fraud and abuse as well as health planning agencies.

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Reflections from the Dean's Office

Robert U. Massey, M.D.

Whenever physicians, hospital administrators, health planners, or regulators meet, the talk soon gets around to the matter of health care costs, and why they seem to be rising faster than anything else. This subject touches dangerous issues and hides aberrant economic and social theories which are rarely acknowledged for fear of misinterpretation. The bureaucrats, representing the secular arm, can write regulations, and want to, but are restrained by a fear that even they do not know enough to prevent their rules from making it all worse.

As we all know now, the cost of health care last year approached 140 billion dollars, and absorbed a larger fraction of the gross national product than ever before. Perhaps for a peace-time economy in an affluent nation, that is as it should be. Some would argue that *should* and *ought* have no more place in economics than in science, but most of us would feel uncomfortable with an amoral approach to the economics of health care. Moral or amoral, the forces of the market do operate, and while the energy for the demand for services rises from many sources, the final common pathway is the physician's signature. Physicians are beginning to recognize that by their orders, prescriptions, and hospital staff meetings they are, in the end, responsible for applying the demand to the sources of supply.

Nevertheless, the hospital administrator will continue to carry the burden of blame, and will be ordered by regulators to control the uncontrollable. Subjected to indiscriminate pressure, he can only pass it down. He will then be accused by his medical staff of compromising the quality of patient care, of caring only for dollars and not for patient welfare. When he points accusingly to the regulators, they will have gone, having no continuing responsibility to anyone but their political masters.

The regulators are not required seriously to regard quality; their decisions have to do with economics, politics, and perhaps the exercise of power. Individually they may worry about quality, especially contemplating their own mortality, but collectively they cannot know enough to make sound judgments, and they know that.

As only the physician can control demand, so only the physician understands about the quality of medical care. He has ways of judging quality open to no one else. Certainly everyone is becoming more knowl-

edgeable about health and medical matters, but unless the whole world becomes doctors, as it may become lawyers, medical care and its quality will remain the affair of physicians. Only they can set the standards, and only they can be certain that standards are being met.

Others are trying and will continue to try. Their efforts will largely fail to accomplish anything, except perhaps to reduce the quality and increase the costs. They do not intend that; they will fail, not because of impurity of intent, but because of lack of knowledge. Only physicians can be clear about what can and cannot be done, about what is good medical practice and what is not, and how to find out when we do not yet know.

Too often in the past, in defining standards, physicians have settled for the pragmatic "usual and customary," depending upon slow evolutionary change to carry the whole system upwards. The twentieth century has given us ample reason to question the inevitability of progress. Standards must be set, and physicians must be prepared to set them high, to make them difficult to attain, and to be ready to enforce them.

Early this year the Massachusetts General Hospital announced a \$600,000 grant from the Milbank Memorial Fund to study the benefits and costs of new and developing technologies in medical care. The Harvard School of Public Health is now issuing a periodic *Newsletter* from its Center for the Analysis of Health Practices. Recently a hospital administrator, who is also a physician, commented that he guessed we could cut the nation's health care costs by one third if we could stop unnecessary procedures and medications. Some studies recently reported suggest that he may be right.

Physicians know enough to begin setting some standards now. The PSRO legislation may be a dispensation to allow time for that. Walter McNerney, pointing to the pitfalls into which this process may fall, has said that "it would be ironic indeed if quality assessment through narrow focus, pedestrian criteria, or otherwise were seen to justify the status quo."¹

Medical schools and their practicing colleagues are charged with this task together. The crisis in cost and the imperative to define quality could provide the energy for progress, or could unleash the regulators. The choice seems clear.

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ROBERT U. MASSEY, M.D., Dean and Professor of Medicine, University of Connecticut School of Medicine, Farmington.

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The President's Page



At a recent meeting of the Organization of State Medical Association Presidents, Dr. Louis Hellman, Administrator Health Services Administration (DHEW) presented health care in this country as involving four major issues: (1) Cost containment (2) Better access to the health care system (3) Some form of health insurance, and (4) Quality Control.

The need for cost containment is a real one. We are acutely aware of it in Connecticut due to recent actions of the Hospital Cost Commission. I have addressed this matter previously and will not dwell upon it, other than to mention again my feeling that it is a most important item, one in which we must take an active interest and a position of leadership. We must keep costs down while we encourage quality care.

I have also devoted a previous president's page to Health Insurance. I would only recall to you that since that time the AMA House of Delegates has reiterated its support for HR 6222 by a better than 2-1 vote. This is the AMA version of National Health Insurance which provides basic and comprehensive health care paid for as much as possible through the private sector with the government providing the insurance for those unable to pay themselves.

Access to the present health care system remains a matter for concern. It is when such access breaks down that we find the development of "Medicaid Mills" and other such organizations which take advantage of the patient's need for care but all too often provide care not up to our professional and ethical standards. There is no better solution to this problem than to incorporate all people into our existing health care system.

The final issue and the one that we can influence the most is quality care. It is our obligation to assure the public of quality. Other agencies are being created to monitor costs. It is necessary that these agencies and physician groups work harmoniously toward the same end. There can be only one judge of quality and that is the physician. Our present PSRO system depends entirely on physician evaluation of medical care. PSRO evaluation and responsibilities need be approached seriously and in the spirit of assuring that proper care is delivered and that the present delivery system is not abused. It is more than likely that in the next few years PSRO will be expanded to reach beyond the hospital. Long term care will be included. Ambulatory care will become the object of study. Privately financed services will be monitored. In effect all medical care will come under review. It is important that this review remain in the domain of the physician. It is important that all questions of the quality of medical care be determined only by the physician. This we can do if we pursue our activities properly through our work with PSRO. The matter of cost containment might then be handled by organizations other than physicians. However, as long as the activities of these groups are based on the decisions of physicians as to what is good medical care, we should have nothing to fear. If we are derelict in our responsibility to define quality care; if we do not present firm and meaningful guidelines, we will be inviting disaster. Harmonious efforts through interactions between physician and lay organizations will preserve our present system. Antagonism is likely to bring about undesirable results.

Hilliard Spitz, M.D.
President

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EDITORIALS

Continuing Medical Education

For several years, concerted, repeated efforts have been made to institute a CME requirement as a condition of membership in the Connecticut State Medical Society. After heated debate, the House of Delegates has concluded that there should be no such requirement at this time. But many medical leaders seem to feel pressure to do something. The pressure emanates from governmental and consumer advocate organs and from the media. Many knowledgeable people are beginning to say that a deep dislike of the professions and of the establishment plays a part in a multifaceted attack on them. Many of our leaders unwittingly aid the sense of pressure with statements such as "If we don't do it, they will do it to us." I believe that if we adopt something poor, inadequate, and obviously in response to external pressure, "they" will be strengthened in their adversary position and may merely do "it" more quickly.

During my attendance at the AMA Biennial Conference on CME last October, many things were evident to me. There was no proof of the effectiveness of CME in any form. The pitifully few studies on the effect of CME on practice behavior were discouraging. Most such programs were didactic, oriented to the teachers' interests and not to the students' needs. Teaching methods were not tailored to the proposed student body. There were never any advance objectives for such programs, let alone pre- or post-program evaluation of the students' knowledge. And there was grave doubt that tests of cognitive knowledge had any but the most tenuous relation to the quality of care delivered by the practicing physician.

A month later, the Institute of Medicine of the National Academy of Sciences released its report, "Assessing Quality in Health Care—An Evaluation," on contract from HEW. Only two of the eleven-man steering committee were identifiable to me as private practitioners. So the recommendation for improving provider performance was a surprise. It states that there should be no mandate for any specific CME technique for improving such performance as there is no existing proof of its effectiveness.

I would also issue an admonition. Limitation and/or denial of membership should always be a matter of the utmost gravity. In the past such humiliation of a member by his peers was an ultimate and effective disciplinary measure. But today there is an additional and immediate result—that of severe economic damage to the subject physician. Through circumstance and chance, to all practical intents professional liability insurance is available in Connecticut only through the Society-sponsored Aetna Plan. I would merely remind that this gives the Society an economic power the injudicious use of which might support a contention of restraint of trade.

If, therefore, there is indeed no evidence of the effectiveness of any given program of CME, the decision of the leadership not to make it mandatory is the correct one. Equally correct are the repeated urgings of this leadership that each member continue a life-long program of self analysis, learning and improvement by whatever methods he or she finds appropriate and useful. This should be our unalterable position until there exists a factual and rational basis for proposed change.

Jerome K. Freedman, M.D.
Vice President, CSMS

Routine Cervical-Vaginal Cytology Smear on Hospital Admission

Elsewhere in this issue of *Connecticut Medicine* is an article entitled "Nurse-Run 'Pap' Smear Hospital Screening" by Fischer, Russo, Matthew and Conway regarding the experience at the Hospital of St. Raphael with the routine cervical-vaginal cytology smear on admission of all female patients over 21 years of age. The hospital of St. Raphael, its medical staff, administration and others involved with the program are to be congratulated for their actions in this regard.

The concept that invasive cancer of the cervix is preventable through early detection of the lesion in the preinvasive stage by cytologic screening is well established. A reduction in the incidence of invasive cervical cancer has been observed in populations subjected to mass cytologic screening.¹ Here in Connecticut we have seen the death rate from cervical cancer reduced by one half in the last 20 years. Still some 20,000 new cases of cervical cancer are predicted for 1976 in the United States.²

What better place than a hospital to apply the knowledge that has been accumulated over the past 20 years on the value of early detection of this lesion and apply the presently available effective modalities of treatment? Although the statistics are not available one wonders how many women who develop invasive cancer of the cervix were admitted to a hospital in Connecticut during the previous 5-10 years.

Although cytology examinations were carried out on some 485,000 women in Connecticut in 1974 this represents slightly more than 26% of the total female population at risk in Connecticut,³ and probably represents a repeat smear in the majority of the patients represented by these statistics.

Of particular interest in the report from St. Raphael's is that a registered nurse and licensed practical nurse were primarily responsible for taking the smears and guiding patient education and information. The Connecticut Cervical Cancer Screening Project of the Connecticut State Department of Health also used a similar approach during its brief existence with good results. This is similar to the program reported by Liu⁴ from the Youngstown Hospital where a laboratory assistant was trained to obtain the specimens. This is an excellent example of the use of non-physicians in an area traditionally the realm of the practicing physician.

The results of the St. Raphael's report although small in number are not dissimilar to Liu's experience at the Youngstown Hospital where they detected 46 positive smears out of 12,384 patients screened with 39 confirmed as being cancer. Of these 39 patients, 31

had primary uterine cancer with 27 of the cervix (including 8 cases of carcinoma in situ) and 4 of the corpus. Of note in their report was that in 17 (55%) of the 31 primary uterine cancer patients the cytologic finding of cancer was an entirely *unsuspected* finding.

It is hoped by the many individuals and groups concerned with the cancer problem that this report from St. Raphael's will encourage other health care institutions in Connecticut to consider routine gynecologic cytology smears on hospital admission of female patients. It would also seem especially important for medical staffs of their respective institutions to consider the use of nurses or other health care personnel to assist in carrying out this vital program. Any efforts to increase the population base of the patients screened should help to move us closer to our ultimate goal, the eradication of deaths from cervical cancer.

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Smoking and the Nonsmoker

Though a vigorous anticigarette smoking campaign has been carried out since the now famous report of the Surgeon General in 1964 resulting in a marked decrease in the proportion of adult cigarette smokers, consumption of cigarettes has continued to rise annually. Along with this increase there has been an accompanying rise in the incidence of lung cancer, particularly in women, so that it is now the leading cause of cancer-related deaths in Connecticut. Significantly the increase in cigarette smoking is largely in teenage girls and women.

The National Cancer Institute has finally decided that a more practical and less punitive approach might be acceptance of the addictive nature of cigarettes with more research on finding a less harmful but satisfying tobacco—a "safe" cigarette. It recently has contracted with the consulting firm of Arthur D. Little to study this. Success, however, will not satisfy

the objections of nonsmokers whose impact in the nonsmoking campaign is gathering momentum. The issues involved in smoking as seen by the health professional, the smoker and nonsmoker are different and need to be clarified.

While the original impetus for the nonsmoking campaign was establishment of the relation between cigarette smoking and cancer of the lung, this emphasis has clouded the viewpoint of the nonsmoker. It is not disease to the smoker that concerns him most, but pollution by smoke of the air he must breathe. Whereas he recognizes the fundamental right of a person to smoke, he is becoming more aggressive about his own right to breathe clean air, unpolluted by smoke whether it be from cigarettes, pipes, cigars or cigarillos.

Most nonsmokers, especially the 30 million adult ex-smokers, sympathetically understand that smoking may be more than a habit having some of the attributes of drug addiction; but they wish smokers to understand and respect their desire to breathe clean air. The smokers' right to smoke does not include a right to pollute the air that others must breathe. The limitation of smoking in planes, restaurants, public places, and especially hospitals is not meant to impinge on smokers' right to smoke, but to prohibit their pollution of the air harmful to the health and well-being of others.

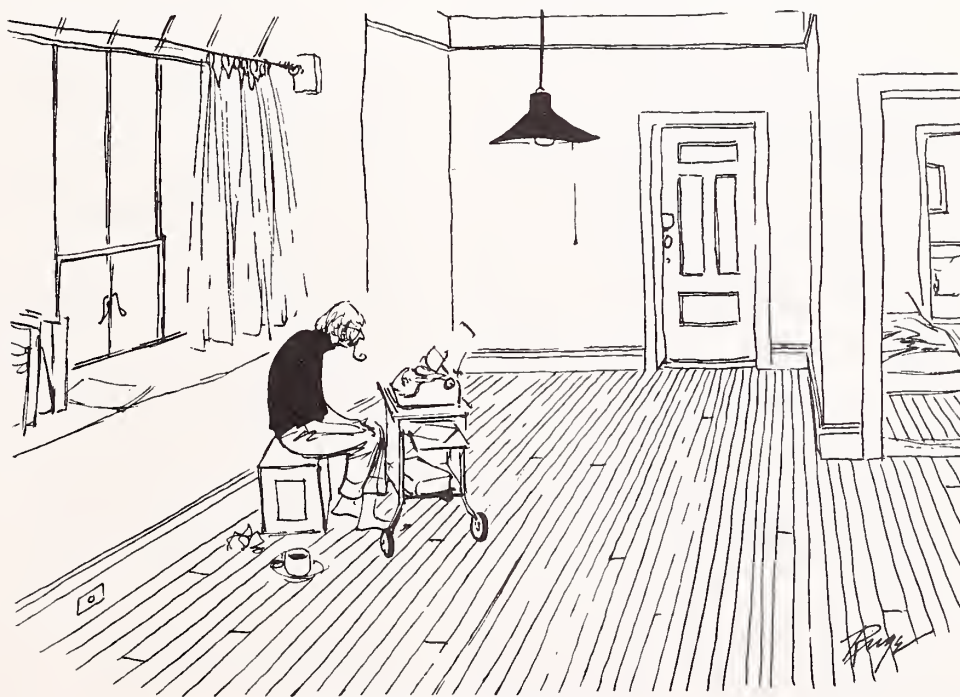
There is little to be gained in reciting mannerisms characteristic of smokers of which they themselves may be generally unaware, but nonsmokers also have

certain characteristics. Most are reluctant to protest when the smoker lights up, even when they are asked if they mind. The rare smoker who does ask really expects a reply in the negative; he usually is surprised at a "yes." Smokers should take it for granted without asking that smoke is objectionable to the nonsmoker, particularly in small crowded rooms. Reaction to the source and type of smoke varies, of course; in a way the public consensus is reflected in rules evolving as to smoking in public aircraft. Nonsmokers have a section reserved for them; even now the Federal Aviation Commission is drawing up regulations for commercial planes—it seems that pipe smoking and cigar smoking will be prohibited, which several airlines are already doing voluntarily. The question apparently is: How much cigarette smoking will be permitted on commercial aircraft?

So let there be no confusion between the campaign being conducted to decrease smoking as a health hazard to the smoker himself and the desire and right of the nonsmoker to breathe clean air. If a non-carcinogenic tobacco were discovered tomorrow, while a tremendous boon to the health and enjoyment of smokers, it would not satisfy the objections of the nonsmoker who wishes to breathe clean air unpolluted by smoke.

To clarify the viewpoint of the generic nonsmoker does not imply he (generic Man including both men and women) is a punitive zealot. Friends, by definition, tolerate bad habits and faults of each other.

Fred Fabro, M.D.



"Chapter one, page one . . ."

SATURDAY REVIEW

BOOK REVIEWS

Philosophical Dimensions of the Neuro-Medical Sciences. Edited by Stuart F. Spicker and H. Tristram Engelhardt, Jr. vi + 274 pp. D. Reidel Publishing Company, Dordrecht-Holland/Boston-U.S.A. 1976. \$29.

The University of Connecticut School of Medicine has pioneered in bringing humanistic studies into medical education. Stuart Spicker, whose Ph.D. is in philosophy, came to UConn in 1973 and moderates the evening Forum on Human Values and Health Care. With H. Tristram Engelhardt, Jr., a physician with a Ph.D. in philosophy, at the University of Texas Medical Branch (Galveston), Dr. Spicker conducts a series of Trans-Disciplinary Symposia on Philosophy and Medicine. *Philosophical Dimensions of the Neuro-Medical Sciences* is the edited proceeding of the second of these symposia.

The participants are leaders in multiple fields and include Karl Pribram, a neurosurgeon and neuropsychologist from Stanford; Arthur Benton, Ph.D., a neuropsychologist from Iowa; and philosophers from UC Berkeley, Princeton, Oxford, and elsewhere. The central topic, the mind-brain or mind-body problem, was first posed by Descartes in the 1600s and has continued to worry philosophers, psychologists, and physicians.

The problem is this: Mental events such as thinking, feeling, remembering, exist as realities of immediate experience. The properties of mental events as experiences cannot be characterized according to the dimensions of the physical sciences, e.g., extension in space, density, velocity, etc. How much does an idea weigh? The contemporary common sense solution is that mental events are really neurophysiological activities occurring in our brains. This works satisfactorily until one tries to look for these events on an oscilloscope. An action potential is not a thought. Can we hope that, if we have just enough action potentials occurring simultaneously and in the right pattern, then we will have a thought?

The first section is entitled Historical Foundations of Modern Neurology. William Bynum, an historian of medicine (University College, London) discusses what he calls "natural theology" and the historical development of the principle of relating structure to function. He singles out the neuroanatomist and phrenologist Franz Gall (1758-1828) as the first "localizer." Gall's contributions include the identification of the first eight cranial nerves and the doctrine that each brain part subserves a distinct mental function, thus inspiring the fascinating and fantastic phrenology busts of the human head with their delineated areas for "consciousness," "sublimity," "amateness," etc. Bynum points out that most phrenologists made no attempt to define the precise interaction between the brain part and the mental category.

In the second historical paper, Arthur Benton, author of many monographs on aphasia, apraxia, and Gerstmann's Syndrome, acknowledges Gall's rôle but identifies Paul Broca as the first *scientific* localizer in the 1860s with his association of aphasia and left hemisphere lesions. He points out that the localization question sparked much controversy in the nineteenth century and quotes the warning of the localizers' most vocal opponent, Hughlings Jackson: "To locate the lesion which destroys speech and to locate the center of language is not the same thing."

The co-editor of the volume, Engelhardt, in his critique, sides with Jackson against the localizers and against substituting the language of sensory-motor integration. Engelhardt's solution to the mind-brain problem accepts the existence and usefulness of two separate languages, one physiological, the other psychological.

Stanford's Karl Pribram, the only neurophysiologist in the volume, offers his theory of "constructional realism" and demonstrates the difficulties of a neuroscientist who tries to do philosophy. According to his model, an idea is "embodied" as a set of relations among neurons in an engram or memory storage. The

memory trace is "realized as an idea when by way of derepression of differential reinforcement a 'viable' outcome can be identified." He seems to side with Sperry (a leader in corpus callosum section work) in seeing the mind-brain issue in terms of "mind as an emergent of brain organization." Marjorie Grene, a well-known philosopher (University of California, Davis), also discusses Sperry's and Gazzaniga's split-brain work and offers the following proposition:

'Mind,' if you want to call it so, develops in the tension between . . . the loosely but subtly interwoven structures of the human brain and the more or less loosely but subtly interwoven structures of the human world (p. 121).

In his critique, Hubert Dreyfus, a philosopher (Berkeley), blasts Pribram as difficult to understand and a "pure Cartesian." He objects to Pribram's hologram theory of mind according to which neural activity produces mental events in a way similar to that by which laser beams can be used to project three-dimensional objects into empty space. He concludes that much of the mind-brain problem can be dissolved by dispelling the "misleading mediation of the mental." No doubt the readers of this volume may come to feel the same way about the misleading mediation of some philosophers.

The most obscure paper is that offered by Hans Jonas, an eminent philosopher (New School for Social Research, New York City). It must be admired for what can only be described as a "cosmic argument." Very few metaphysicians have dared to offer an actual model of the interaction between mind and brain, and Jonas deserves credit for attempting it. He refutes what is known as the epiphenomenalist view according to which mental events are seen as noninterfering by-products of physical and, in particular, neurophysiological activity. He offers the following "hypothetical fiction":

". . . at the 'edge' of the physical dimension, marked by such peaks of organization as brains, there is a porous wall, beyond which lies another dimension. . . . Between input and output there is interposed a process of an entirely different order from the physical one . . . so it feeds back into it what has gone through the transformation of subjectivity" (pp. 158-160).

Stuart Spicker, a student of Jonas some years before at the New School, does not tackle this model directly, pointing out that Jonas himself refers to it as a speculative model or "hypothetical fiction." After some apology to his previous teacher he focuses on the fact that Jonas has still not offered a satisfactory account of just what sort of "psychical causality" exists between the physical dimension and subjectivity. He turns to the phenomenology of Husserl according to which "the *sense* 'mind' and the *sense* 'body' are distinct as sets or systems of relations" (p. 171) and concludes with a mysterious but intriguing suggestion: "Thus mind and body are distinct only in thought, though inseparable in fact" (p. 171).

The Round Table discussion at the end of the two-day conference included a statement by the only neurosurgeon on the program. Samuel Greenblatt (Albert Einstein College of Medicine), speaking for neuroclinicians in general, said: "Most of us will readily admit that we are stumped by the problem of Cartesian dualism. But when given a little elbow room, we ignore the problem. We function as integrationists or parallelists or something like that" (p.243).

The Second Trans-Disciplinary Symposium did not resolve the mind-brain problem, but it represents one of the few attempts to bring philosophers and neuroscientists together to exchange perspectives.

David R. Hubbard, Jr.

University of Connecticut School of Medicine,
Class of 1977

**185th ANNUAL MEETING
CONNECTICUT STATE MEDICAL SOCIETY
HARTFORD HILTON HOTEL
10 Ford Street, Hartford, Connecticut
April 27, 28, 1977**

**PRELIMINARY PROGRAM
WEDNESDAY, APRIL 27**

**ANNUAL MEETING OF THE HOUSE OF DELEGATES
BALLROOM————MEZZANINE**

Presiding: Timothy F. Nolan, Greenwich, speaker of
the House;
David A. Grendon, Sharon, Vice-Speaker
of the House.

7:30 Registration of Delegates
8:30 Call to Order—Opening Session
Reference Committee Hearings
1:15 Luncheon—Terrace Room, Mezzanine
3:00 Call to Order—Final Session
6:16 Adjournment

**ANNUAL DINNER OF THE SOCIETY
Wednesday, April 27**

6:30 Social Hour
7:30 Dinner

**THURSDAY, APRIL 28, 1977
GENERAL SCIENTIFIC PROGRAM**

MORNING SESSION

8:15 REGISTRATION—Mezzanine
8:30-10:00 MEETINGS OF SECTIONS OF THE
SOCIETY AND GUEST ORGANIZA-
TIONS

10:00 INTERMISSION TO VISIT EXHIBITS—
Mezzanine

BALLROOM

10:20 CALL TO ORDER AND WELCOMING
REMARKS

President, Connecticut State Medical
Society
Presiding: William F. Eckhardt, Jr.,
New Canaan

10:30 CURRENT CONCEPTS OF CALCIUM
REGULATION—

Lawrence G. Raisz, Professor of Med-
icine, University of Connecticut
School of Medicine,
Farmington, Conn.

11:15 NEPHROLITHIASIS—PATIENT EVALUA-
TION WITH EMPHASIS ON SPECIFIC
DIAGNOSIS

Arthur E. Broadus
Assistant Professor of Medicine
Yale University School of Medicine
New Haven, Conn.

12:00 DISCUSSION: QUESTIONS AND
ANSWERS

12:30 INTERMISSION TO VISIT EXHIBITS

1:00 LUNCHEON—Terrace Room

AFTERNOON SESSION

2:00 APPLICATIONS OF ADVANCES IN
THYROID PHYSIOLOGY TO CLINICAL
DIAGNOSIS

P. Reed Larsen, Chief, Thyroid Unit
Peter Bent Brigham Hospital
Boston, Mass.

2:45 NODULAR GOITER AND THYROID
CANCER

Colin G. Thomas, Jr.
Professor of Surgery
University of North Carolina
Chapel Hill, North Carolina

3:30 INTERMISSION TO VISIT EXHIBITS

4:00 MEETINGS OF SECTIONS OF THE
SOCIETY AND GUEST ORGANIZATIONS

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William R. Richards, M.D.
Executive Director
Josephine P. Lindquist
Associate Executive Director

Robert J. Brunell
*Assistant Executive Director
Scientific Activities*

CALL ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1977 Annual Meeting of the House of Delegates will be held at the Hartford Hilton Hotel, Hartford, commencing at 8:30 A.M. on Wednesday, April 27.

Hilliard Spitz, President
Timothy F. Nolan, Speaker of the House
Louis C. Backhus, Secretary

INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides:

Resolutions may be introduced by any Active or Life Member of The Society, in compliance with the following provisions.

- a. All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.*
 - b. Component county associations whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc. be considered regular business if they are received later than fifteen days prior to the date of the meeting.*
 - c. Reports, recommendations, resolutions or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered as regular business.*
 - d. Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for consideration by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provision of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.*
-

Summary of Actions

Council Meeting

Thursday, January 20, 1977

I. Attendance

Present in addition to the Vice Chairman, Dr. G. W. Van Syckle, were: Drs. Spitz, Freedman, Backhus, Johnson, Nolan, Hess, Canzonetti, Bradley, Cramer, Kamens, Harkins, James, Mendillo, Whalen, McGarry, Parrella and Zlotsky.

Also present were: Mrs. Lindquist, Mrs. Arafah (Auxiliary), Mr. Tomat, Mr. Sweeney and Dr. Richards.

Absent were: Drs. Friedberg, Grendon, Fabro, Robinson, Krinsky, Sonnen, Beck, Ahrens, Sadowski, Vidone, Magram, Eslami, Barrett and Middleton.

II. Routine Business

Approval of Minutes

It was VOTED to approve the minutes of the meeting of December 15, 1976, as published and distributed.

Life Memberships

It was VOTED to approve applications for Life Membership received from the following Active Members:

Frederick Kessler, 100 York Street, New Haven
Gerald Krosnick, 2 Church Street So., New Haven
Theodore Lidz, 25 Park Street, New Haven
Leo Litter, 21 Woodland Street, Hartford
John C. Shull, 2 Redstone Drive, Simsbury
Herbert Wyatt, 135 Whitney Avenue, New Haven
J. Alfred Fabro, 94 Church Street, Torrington

III. Old, New and Special Business

Cumulative Minutes of Committee Meetings

Concerning the 10/5/76 minutes of the Committee on Emergency Medical Services and EMS, it was VOTED that the Council express concern re the reported proposal to create an ever-enlarging bureaucracy to supervise the operation of emergency medical services in Connecticut and that the Committee be requested to advise the Council as to the necessity thereof.

Physician Liability Coverage as Criterion for Hospital Privileges

It was VOTED to receive as information a subject communication furnished by the American Medical Association which recounted the situation that exists in a number of other states where hospital boards of trustees have made, or tried to make, the status of a physician's professional liability insurance coverage a criterion for hospital staff privileges. It was further VOTED to receive as information a proposed statement as follows: "The Council of the Connecticut State Medical Society is aware of a growing tendency of hospital boards of trustees to make the ownership of professional liability insurance, often in specified amounts, a condition for the granting or continuance of staff privileges. The Council, acting for the Society, urges that the criteria of professional competence and ethical conduct be the only ones applied in the matter of granting or continuing hospital staff privileges. The Council is aware that non-insurability against professional liability may, though by no means certainly, indicate a weakness in the physician's competence. In light of such a possibility, the Council urges that hospital boards of trustees call upon the hospital's medical staff to investigate the circumstances of a physician's non-insurability, or lack of liability coverage, so as to be as certain as possible whether his/her professional competence is in question before passing judgment on granting or continuing his/her hospital staff privileges."

Finally, the Council VOTED to refer the foregoing policy statement to the Committee on Professional Liability for evaluation and report.

Resignations, Appointments, Etc.

(a) Committee on Drug Abuse Educational Programs:

It was VOTED to appoint to Committee membership Louis Della Valle, Hamden.

(b) Committee on Continuing Medical Care and Rehabilitation:

It was VOTED to take actions on Committee membership as follows: Accept the resignation of Ian R. Lawson, Danbury, as Committee chairman (he remains a member); appoint Marvin Garrell, Fairfield, as Committee chairman

(he is already a member); appoint A. Gerard Mack, Trumbull, as a Committee member.

Summary of Actions, AMA House of Delegates, 12/5-8/76

It was VOTED to receive as information the subject "Summary", prepared by the office of the AMA Executive Vice President; also, a series of verbal reports presented principally by E. Tremain Bradley, AMA Delegate. Stemming from discussion of this information, the Council took actions as follows:

(a) **Proposal to Have Full-time, Salaried AMA President:** VOTED to express disapproval of this proposal and so inform the AMA Board of Trustees and the Council on Long-Range Planning and Development (to which it has been referred for study and report to the next AMA meeting.

(b) **Relative Value Scales:** VOTED to support, and so notify the AMA Board of Trustees, a subject resolution adopted by the AMA House of Delegates as follows:

RESOLVED: That the American Medical Association continue to pursue through all appropriate means the introduction and enactment of national legislation designed to confirm the authority to develop and use relative value scales and studies by the medical profession.

(c) **Coordination of Legislative Activities of AMA-State Societies-County Associations:** VOTED to refer to the SCMS Committee on Legislation for evaluation, feasibility study and report, a subject resolution referred by the AMA House to the Board of Trustees (for report to the 1977 Annual Convention of the AMA House of Delegates) as follows:

Resolution 36: This resolution urges the Association's officers, staff, council and committee chairmen to undertake discussions with officers and staff representatives of state medical societies to bolster federal legislative relationships through 'Key Man' legislative programs.

(d) **AMA Direct Billing for Dues to AMA Members:** VOTED to inform AMA that the Society has no objection to direct billing of AMA members in Connecticut, and to direct Staff to advise AMA of any "problems" that the Society might encounter as a result of such billing, if any. Direct AMA billing is proposed for 1978.

(e) **Medical Student Liability Insurance:** Voted to bring to the attention of the deans of the two medical schools in Connecticut a subject resolution that is under study by the AMA Board of Trustees and Council on Medical Education (for report to the

1977 Annual Convention of AMA House of Delegates) as follows:

RESOLVED: That the American Medical Association encourage every medical school to try to make comprehensive liability (insurance) coverage available to its students while they are participating in the core curriculum of their respective medical schools; or extensions of this core curriculum that have been approved by the deans of their respective medical schools.

The Council further VOTED to ask the deans whether such liability coverage is available to students at their respective institutions.

Request for Authorization to Form Section on Preventive Medicine

Being assured by Staff that the application was in order, the Council VOTED to approve the formation of a new combined Section on Preventive Medicine and to recommend approval by the House of Delegates. In a related action, the Council VOTED to approve discontinuance of the existing Section on Occupational Health and Section on Preventive Medicine and Public Health, and to recommend similar action by the House of Delegates.

Further Discussion on Hospital—CHHC Controversy

(a) **Committee on Hospitals:** It was VOTED to receive as information the minutes of a Committee meeting held on 1/5/77 at which various aspects of the subject controversy were explored in limited degree. The Committee recommended that the Council study, and, if feasible, support in principle the legislative measures to revise and restructure the Commission on Hospitals and Health Care that are being presented to the General Assembly by the Connecticut Hospital Association. No action was taken on the Committee's recommendation re the CHA proposals.

(b) **Committee on Statewide Medical Planning:** It was VOTED to receive as information a subject report submitted by the CSMP, which offered for Council approval a general policy statement on rising costs of health care services and the need to have a regulatory agency "if the people of Connecticut are to have available to them all essential hospital services at the most reasonable cost possible". No action was taken to approve the statement. (AMB 1/20/77 "F")

Noting that a number of subject bills, including those of CHA, would be under consideration by the 1977 General Assembly, the Council VOTED that the Society take positions of opposition or support as follows:

(a) **Makeup of Commission:** Oppose any and all bills that advocate a change in the makeup of the Commission, as it is at present, and/or change the method of appointment of Commission members.

(b) **Discontinuance of Hospital Services:** Oppose any and all bills that would empower the Commission to order the discontinuance of an existing hospital service.

In a final subject action, it was VOTED to invite Mr. F. Bernard Forand, Executive Director of the CHHC, to join the Council members at the next meeting to discuss, in particular, the following subjects: the various legislative proposals relating to the Commission; plans for Commission activities that may be anticipated in 1977; his thoughts on limiting the jurisdiction of the Commission to "rate-setting".

Report on Rep. Moffett's Investigation of Medicare Acceptance of Assignment

It was VOTED to receive as information the minutes of a 1/6/77 meeting of the Committee on Peer Review Systems, at which an investigative study was begun as to why the acceptance of assignment by physicians under Medicare B in Connecticut (40%) is lower than the rate (50-70%) in the other New England states. Although a considerable amount of data (supplied by Connecticut General) was carefully examined, and a number of possible explanations for the reported disparity were contemplated, the Committee was unable to reach any definitive conclusions in the matter. Further study, including a possible survey of the membership, will be undertaken by the Committee at an early date.

It was also VOTED to receive as information a verbal report presented by the President, Dr. Spitz, on his participation in a 1/14/77 semi-public meeting called by Rep. Moffett to inquire into the subject of the low acceptance of assignment rate in Connecticut. Dr. Spitz reported that the meeting was conducted on a high level; that no one—including Mr. Moffett—appeared to have knowledge as to *why* the situation is as it is; and that he had pledged the Society's full cooperation to any responsible effort to try to come up with answers to the subject question.

Report—Advisory Subcommittee on Publications

It was VOTED to accept for filing a report of the Subcommittee on its study of the feasibility of transferring to a newsletter some or all of the items of "Society business" that are currently being published in the Journal. It was further VOTED to approve recommendations of the Subcommittee as follows:

(a) That, from a fiscal standpoint, it would not be feasible to publish "Society business" in a monthly

newsletter; that, therefore, "Society business" continue to be published in the Journal.

- (b) That the Editor seek to develop a mechanism by which items of "Society business" (such as summaries of Council and House of Delegates actions) can be published in the Journal in a more timely fashion; i.e., sooner than the 6-8 weeks that obtains at present.
- (c) That whether to utilize the "President's Page" each month be left to the discretion of the President.
- (d) That the publishing of lists of Student Members (elected by the Council) be discontinued.

A recommendation that the Society pay the Journal for publishing two pages of Placement Service notices monthly, thus providing an additional 24 pages per year for scientific and editorial content, was referred to the Fiscal Subcommittee for study and report at the next Council meeting.

Certificate of Service for Assistant Executive Director

It was VOTED to have prepared, for presentation at the 1977 Annual Meeting, a certificate in recognition of the services rendered to the Society by Mr. Leonard R. Tomat, Assistant Executive Director. Mr. Tomat is leaving the employ of the Society in February to become Executive Secretary of the Fairfield County Medical Association.

Summary of Actions

Council Meeting

Wednesday, February 16, 1977

Attendance

Present in addition to the Vice Chairman, Dr. G.W. Van Syckle, were: Drs. Spitz, Friedberg, Freedman, Backhus, Johnson, Nolan, Hess, Canzonetti, Cramer, Fabro, Kamens, Harkins, James, Mendillo, Sonnen, Whalen, McGarry, Beck, Ahrens, Sadowski, Vidone, Magram, Eslami, Parrella, Barrett, Zlotzky and Middleton.

Also present: Mrs. Lindquist, Mr. Sweeney, Mr. Brunell, Dr. Bongard (UConn) and Dr. Richards. Mr. Robert J. Brunell was introduced by the Chairman as the new Assistant Director.

Absent were: Drs. Grendon, Bradley and Krinsky.

In Memoriam—David Robinson, M.D.

Following the call to order, and before proceeding with the business meeting, the Chairman of the Council asked the members of the Council to stand for a moment of silence in memory of Dr. David Robinson, Councilor from Hartford County, who died on January 22, 1977.

Routine Business

Approval of Minutes

As published and distributed, it was VOTED to approve the minutes of the meeting of January 20, 1977.

Life Memberships

It was VOTED to approve applications for Life Membership received from the following eligible Active Members:

Hyman D. Brier, 2574 Main Street, Bridgeport

William C. Carey, 377 Broad Street, Meriden

Russell F. Colburn, 1416 Bedford Street, Stamford

Frederick W. Finn, 4 Dearfield Drive, Greenwich

Grover A. Lyon, 2009 North Avenue, Bridgeport

Thomas S. McLean, Jr., Village Green, 7300 Rte. 60, Vera Beach, Fla.

Pasquale A. Piccolo, 114 Sherman Avenue,

New Haven

John J. Poutas, 46 No. Ridge Road, Old Greenwich

Alan Rozen, 113 Howe Street, New Haven

Morris Sulman, 203 Montauk Avenue, New London

Election of Student Members

It was VOTED to elect to Student Membership four Connecticut residents who are enrolled in American medical schools.

Date of Next Meeting

The Vice Chairman set the date of the next Council meeting for Thursday, March 10, 1977.

Old, New and Special Business

CSMS Medical Student Financial Aid Fund

It was VOTED to remove from the table (tabled 1/20/77) the following motion: "That the Council request from the Deans of YUSM and UCMS current itemized listings of medical students at their respective institutions who have loans outstanding (from the Fund) and the purposes thereof, the identification of the students to be by account number, *not* by name." It was further VOTED to refer the motion to the Committee on Cooperation with the Medical Schools of Connecticut for consideration. The minutes of several recent meetings of the Committee indicate that the medical schools may wish to change the *modus operandi* of the original administration of the Fund. It is understood that if proposals for such change are finalized, they will be submitted to the Council for approval.

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

***INDICATIONS.** Based on a review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the indications as follows:

Effective: Management of nausea and vomiting and dizziness associated with motion sickness.

Possibly Effective: Management of vertigo associated with diseases affecting the vestibular system.

Final classification of the less than effective indications requires further investigation.

CONTRAINDICATIONS. Administration of Antivert (meclizine HCl) during pregnancy or to women who may become pregnant is contraindicated in view of the teratogenic effect of the drug in rats.

The administration of meclizine to pregnant rats during the 12-15 day of gestation has produced cleft palate in the offspring. Limited studies using doses of over 100 mg./kg./day in rabbits and 10 mg./kg./day in pigs and monkeys did not show cleft palate. Congeners of meclizine have caused cleft palate in species other than the rat.

Meclizine HCl is contraindicated in individuals who have shown a previous hypersensitivity to it.

WARNINGS. Since drowsiness may, on occasion, occur with use of this drug, patients should be warned of this possibility and cautioned against driving a car or operating dangerous machinery.

Usage in Children: Clinical studies establishing safety and effectiveness in children have not been done; therefore, usage is not recommended in the pediatric age group.

Usage in Pregnancy: See "Contraindications."

ADVERSE REACTIONS. Drowsiness, dry mouth and, on rare occasions, blurred vision have been reported.

More detailed professional information available on request.

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Progress Report—FTC Complaint

It was VOTED to receive as information a subject report presented verbally by the Executive Director. The principal matters touched upon were: Postponement of the hearing from June until "after Labor Day"; the petition of AMA-CSMS-NHCMA that the FTC reconsider its action to issue a complaint initially and possibly to withdraw it.

Report—Subcommittee on Preliminary Study of Nominations

With several amendments, it was VOTED to approve the report of the Subcommittee and to transmit a complete slate of nominees to the House of Delegates for election, with Council recommendation for approval by the House.

In conjunction with taking the foregoing action, it was further VOTED to recommend to the House of Delegates for approval changes in standing committee composition as follows:

- (a) *Committee on Program of the Scientific Assembly*: Eliminate the restriction that no two members of the Committee may be engaged in the same type of practice.
- (b) *Committee on Professional Liability*: Eliminate the provision that the chairmen of the Committee on Public Relations and the Committee on Hospitals, by title, are automatically members of the subject Committee.
- (c) *Committee on Statewide Medical Planning*: To eliminate the provision that the Society's representatives to the Connecticut Regional Medical Program (CRMP), by title, are automatically members of the subject Committee. *N.B.*: CRMP is no longer in existence.

Presentation re Commission on Hospitals and Health Care

By invitation, Mr. F. Bernard Forand, Executive Director of the CHHC, joined the Council to make a verbal presentation, supplemented by charts, explaining the formula or guideline system used by the Commission to screen and approve hospital budgets for 1976-77. He indicated that a similar but somewhat more stringent system has been used experimentally in Rhode Island for two years of a three year study in which sixteen acute care hospitals in R.I. had participated voluntarily, and that a system of this sort is being considered by the Congress as a prelude to any national health insurance plan that may be enacted. He denied that the budget cuts effected by the Commission put a "cap" on hospital expenditures, noting that provision has been made that income generated by services in excess of those budgeted for may be used to cover the additional costs of furnishing the

greater number of services. Following his presentation, Mr. Forand responded to questions posed by the Council. The speaker also touched briefly on various legislative proposals to change the composition of the Commission, to alter the present qualifications of its executive director and to limit its jurisdiction and authority.

Finally, it was VOTED to send Mr. Forand a letter of thanks for his presentation and to commend Sidney L. Cramer, Hartford, who suggested (1/20/77) that Mr. Forand be invited to appear.

Resolution re "Soviet Health Professionals"

It was VOTED to adopt, as amended by the Council, a subject resolution as follows:

"RESOLVED: That the Connecticut State Medical Society call for the immediate end to the abuse of psychiatry for political purposes in the USSR, and instruct its officers and representatives to transmit this resolution to the President of the United States, the Secretary of State, Connecticut's Representatives and Senators and to the Secretary-General and Premier of the USSR as well as to the Soviet Ambassador to the United States."

Communication—NLCMA Board of Trustees re New Medicare-Medicaid Billings

It was VOTED to receive as information a communication from the New London County Association's Board of Trustees, which called attention to the excessive demands on physicians' time caused by the new "double billing" procedures that must be complied with in submitting claims for Medicaid patients who are entitled to Medicare benefits. Since the new procedures were imposed by the Department of Social Services, the Council VOTED to instruct the Liaison Committee with DSS to vigorously protest and seek immediate relief from the new Medicare-Medicaid billing procedures, in that they constitute an unwarranted burden on physicians and will undoubtedly discourage additional physicians from participating in the Medicaid program. It was further VOTED to invite Frederick C. Barrett, Norwich, to join the Liaison Committee when this matter is discussed with Commissioner Maher and/or his staff.

Nominee for Honorary Membership

It was VOTED to nominate George E. Palade, M.D., Professor and Chairman of the Department of Cell Biology at YUSM, for election as an Honorary Member of CSMS by the House of Delegates at the April meeting. Dr. Palade has been the recipient of many national and international awards for his scientific achievements in microbiology.

Communication—NHCMA Board of Governors re CMS Policy

It was VOTED to receive as information the copy of a communication (dated 2/8/77) from the NHCMA Board to the President of CMS expressing objection "to CMS' retroactive reduction in maximum allowable payments. . . ." It was stated that CMS has reduced payment for suction curettage performed in an office setting from \$125-150 to \$25, and that such a reduction will encourage patients to opt for costly hospital admissions rather than ambulatory operative treatment. Following a period of discussion of the issue, the Council further VOTED to inform CMS of its support of the position of the NHCMA Board of Directors on the grounds that such position is in keeping with CSMS policy that equal payments should be made for equal services, whether the services are performed in an in-patient or ambulatory setting.

Request for Panel of Examiners—Connecticut Medical Examining Board

It was VOTED to receive as information a letter from the Acting Executive Director of the CMEB which requested the Council to cooperate in compiling a list of physicians "who could be called upon in the future to conduct physical or mental examinations on physicians being investigated by the Board" by suggesting the names of five physicians who could perform physical examinations and five physicians having expertise in psychiatry (to perform mental examinations).

It was further VOTED to ask the President, the President-Elect, the Vice President and the Vice Chairman of the Council to contact the presidents of the component County Associations to obtain from them the names of physicians that the Council could submit to the Examining Board.

N.B.:The foregoing is a summary of the proceedings and actions of the Council on January 20 and February 16, 1977. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.

Position Statement on Health Manpower

Prepared by
CONNECTICUT JOINT PRACTICE
COMMITTEE

Current trends in health care delivery seem to perpetuate fragmentation of functions, creating a large variety of health care personnel who have a narrow range of skills. Patient care should be so fragmented *only* when the result is to increase quality of outcome, patient satisfaction and cost effectiveness.

When a new function *is required*, existing classes of personnel should be evaluated in order to ascertain whether the function of any could be redefined and expanded, rather than inventing a new type of health worker.

Should a new field be essential for patient care, universal criteria should be established for training programs designed to provide students with those skills and qualifications that are relevant, viable and clinically useful to the new field. These criteria must be consistent with maintaining equal or improved standards of performance and delivery of health care services. In addition, national standards for evaluation and certification of each new field, must be established promptly to avoid role confusion.

Unfortunately, certain recent trends in preparing health workers (often at public expense) violate the above principles. These trends have produced new workers with too limited a range of tasks. In addition, we have witnessed the discarding of innocent new workers as their narrow task is abandoned. This is both inhumane to the worker and inefficient for the health care system. Transfer of occupational functions from one group to another with *no* net improvement in the quality or economy of patient care makes no sense in the cost controlled environment in which we now live.

Our goal should be to place each current or new type of health manpower to the test of the health care needs of the patient, effectiveness in delivery of that care, efficiency in delivery of that care, and economy, in that order.

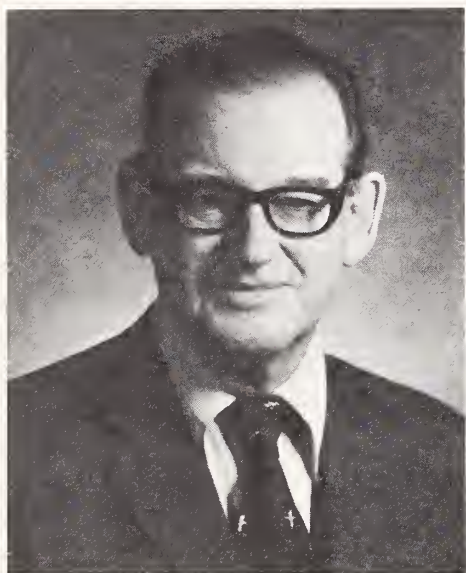
Kenneth F. Brandon, M.D., Chairman
Connecticut State Medical Society

Dennise Heinemann, R.N., Chairman
Connecticut Nurses' Association

Adopted by the CSMS Council
and the CNA Board of Trustees

OBITUARY

JOHN E. BURNS, M.D.
1915 — 1976



Dr. John E. Burns attending surgeon on the staff of St. Francis Hospital died on December 31, 1976. Born in Milford, Massachusetts where he attended school, he was a graduate of the College of the Holy Cross, Worcester, Massachusetts and Tufts Medical School. During World War II, he served as a Lieutenant Colonel in the United States Army Medical Corps.

His internship at Boston City Hospital was followed by his surgical residency at Worcester City Hospital and St. Francis Hospital. He served on the surgical staff at St. Francis Hospital for 28 years and was also on the courtesy staff of both the Hartford and Mt. Sinai Hospitals. He was a surgical consultant at the State Veterans Hospital in Rocky Hill.

Dr. Burns was a Diplomate of the American Board of Surgery, a Fellow of the American College of Surgeons. He was also a member of the Hartford County Association and the Connecticut State Medical Society.

Dr. Burns was a man possessed of a gentle, kindly nature who was painstaking in his work and devoted to his patients. During his tenure as director of surgery at St. Francis Hospital, he sacrificed much of his personal life to extend his time and efforts to the residents and their programs. An avid sports enthusiast, he had instant recall of many memorable sporting events and athletic figures. His passing has created a great void in the lives of his patients as well as his many friends and colleagues. He is survived by his wife, Dorothy Dillon Burns of West Hartford.

Timothy L. Curran, M.D.

In Memoriam

Chapnick, Morton H., Jefferson Medical School, 1932. Dr. Chapnick was a general practitioner in the Windham area since 1933. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Chapnick died December 31, 1976, at the age of 73.

Friedman, Irving, Yale Medical School, 1933. Dr. Friedman was a senior clinical professor of obstetrics and gynecology at Yale University. From 1942 to 1946 he served in the Army as chief of surgery, acting chief of surgery service, and in obstetrics and gynecology. He was discharged with the rank of lieutenant colonel. In 1940 he became a member of the clinical faculty at Yale Medical School and on July 1, 1972, he was promoted to clinical professor of obstetrics and gynecology at Yale School of Medicine. He was a member of the New Haven County Medical Association and the Connecticut State Medical Society. Dr. Friedman died January 7, 1977 at the age of 69.

Harris, Augustus L., Long Island College of Medicine, 1914. Dr. Harris was a general practitioner in the Middlesex area since 1948, until his retirement several years ago. He was a former consultant urologist to Middlesex Memorial Hospital in Middletown and affiliated with Lawrence and Memorial Hospitals in New London. He was a member of the Middlesex County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Harris died December 12, 1976, at the age of 86.

Longo, Vincent F., Long Island College, 1943. Dr. Longo was a surgeon in the New Haven area since 1947. He served in the U.S. Army Medical Corps from 1944-1946, and was a member of the New Haven County Medical Association and the Connecticut State Medical Society. Dr. Longo died January 16, 1977, at the age of 63.

Sokolski, Edward J., Univ. of Maryland Medical School, 1945. Dr. Sokolski was a obstetrician-gynecologist in the Fairfield area since 1950. He was a former president of the Danbury chapter of the American Cancer Society and was currently serving as a medical advisor to the Society. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Sokolski died December 3, 1976, at the age of 57.

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiry of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511, (203-865-8622).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine*.

PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

Internal Medicine: Board eligible. Available July 1977. Prefers medium or small sized community. Will consider ER work. M.D. from the University of the East in the Philippines. FLEX. Completing training at Kingsbrook Jewish Medical Center, Brooklyn, New York. Silvestre B. Almirol, Jr., M.D., 100 East 92nd Street, Apt. 3K, Brooklyn, NY 11212.

Internal Medicine: Available June 1977. Group practice. Board eligible. M.D. and training from University of Iowa. 30 years old. Charles W. Graeber, M.D., 2929 Radcliffe, Iowa City, IA 52240.

Internal Medicine: Available July 1977. Board eligible. Desires medium or small sized community in a small group setting. Dartmouth graduate. M.D. from Downstate Medical School. Internship and residency in Buffalo. 29 years old. Married. Mark C. Hamilton, M.D., 149 Creekside Drive, Tonawanda, NY 14150.

Internal Medicine: Board eligible. FLEX. Available July 1977. Completing training at Queens Hospital Center, Jamaica, NY. A.N. Memon, M.D., 164-08 85 Ave., Jamaica, NY 11432.

Internal Medicine: Board eligible. Available July 1977. Completing training at Wilmington Medical Center. D.O. from Philadelphia College of Osteopathic Medicine. 28 years old. Married. Desires large community in solo, group or associate practice. Harvey T. Starr, D.O., Colony North Apts. 2 Colony Blvd., #139, Wilmington, DE 19802.

Internal Medicine: Board eligible. Available July 1977. M.D. from University of Virginia. Postgraduate training at Nassau County Medical Center. Desires group practice. Joseph L. Verdirame, M.D., 200 Carman Avenue, Apt. 6G, East Meadow, NY 11554.

Internal Medicine: Primary Care with some teaching. Available September 1977. Board eligible. Completing special training at University of Rochester. 33 years old. M.D. from Jefferson Medical College. Solo, group or associate practice. Edward B. Yellig, M.D., 341 Mulberry Street, Rochester, NY 14620.

Internal Medicine: Primary Care. Desires university affiliated community hospital. Special interest in Fairfield County. Available July 1977. Board eligible. M.D. from Medical College of Virginia. Completing residency at Norwalk Hospital. Victor J. Tricarico, M.D., 23 Woodbury Avenue, Norwalk, CT 06850.

Internal Medicine: Presently available. Connecticut license. FLEX. Board eligible. Presently in practice. Wishes to return to Connecticut. Trained at Norwalk Hospital. J.K. Patel, M.D., c/o R.D. 1, Rt 57, Box 1., Washington, NJ 07882.

Internal Medicine: Connecticut license. Desires institutional location. Interned at Danbury Hospital. Available July 1977. R.C. Patel, M.D., 5 Franklin Avenue, Apt. C-7, Nutley, NJ 07110.

Internal Medicine: Desires group or associate practice in medium or small community. M.D. from Tufts. Internship and residency at Medical Center of Western Massachusetts. Available in July 1977.

Personal interview can be arranged. Board eligible. Robert P. Rosenthal, M.D., Lake Paradise, Monson, MA 01057. (413-267-3861).

Internal Medicine: Board certified. 30 years old. Presently in practice but wishes to return to the East. Group or associate practice. M.D. from Downstate New York. Interned at Kings County and residency at Tucson. Available on or before July 1977. Jeffrey I. Selwyn, M.D., 7111 Pampa Place, Tucson, AZ 85704.

Internal Medicine: Available August 1977. New Haven native. Completing active duty in U.S. Army. M.D. from Duke. Internship and residency at Presbyterian-University of Pennsylvania Medical Center. Desires group practice. David A. Levitin, M.D., Department of Internal Medicine, Walson Army Hospital, Fort Dix, NJ 08640.

Internal Medicine: Group practice. Available July 1977. Completing training at Stamford Hospital. 28 years old. M.D. from George Washington University. Board eligible 6/77. Complete resume on file at CSMS. IM—MMD.

Internal Medicine: Available July 1977. Desires Fairfield County area. M.D. from Albert Einstein Medical College. Trained at Montefiore. Board eligible. Desires group or associate practice. Steven Meyerson, M.D., 155 South Broadway, Tarrytown, NY 10591.

Internal Medicine: Connecticut license. Available now. 46 years of age. M.D. from University of London. Fellow of the Royal Society of Medicine. (FLEX in 1971.) Has been associated with public health clinics in New York State. Interested in Public Health, institutional or industrial positions. David C. Hutfield, M.D., Box 963, Norwich, CT 06360.

Internal Medicine: 31 years old. Connecticut license. Available August 1977. Two years in pediatrics at Albany Medical Center. Completing program in internal medicine at St. Mary's Hospital, Waterbury. Wishes to remain in Connecticut. Ronald D'Andrea, M.D., 224-E Oakville Ave., Waterbury, CT 06708 (1-573-9795).

Internal Medicine: Connecticut license. FLEX. Available July 1977. Board eligible. Desires group practice. Has had ER experience. Resume on file with CSMS. IM-GMD.

Internal Medicine (Cardiology): Group or associate practice. Board certified. 32 years old. Married. Presently instructor at the University of Rochester. John S. Zesk, M.D., University of Rochester School of Medicine, P.O. Box 679, Rochester, NY 14642.

Internal Medicine (Cardiology): Board certified. Solo or associate. Completing fellowship at Beth Israel in NYC. S.H. Nanavati, M.D., 353 E. 17th Street, #9B, New York, NY 10003.

Internal Medicine (Cardiology): Available July 1977. Completing fellowship at Duke Medical Center. M.D. and training at University of Pennsylvania. 32 years old. Board certified in IM. Board eligible in cardiology. Burton Silverstein, M.D., 504 Sharon Road, Chapel Hill, NC 27514.

Internal Medicine (Cardiology): Special interest in echocardiography, both in performing and interpreting echocardiograms. M.D. and all training at Cornell-New York University. Senior residency at University of Michigan. Fellowship at Strong Memorial Hospital. Board certified in 1975. Karl C. Sze, M.D., 252-C Quinby Road, Rochester, New York 14623.

Internal Medicine (Cardiology): Group practice. Trained in invasive and non-invasive cardiovascular techniques. M.D. from University of California. All post graduate training at University of Iowa. Board certified. Available July 1977. M.A. Thompson, Jr., M.D., 1417 Derwin, Iowa City, Iowa 52240.

Internal Medicine (Cardiology): Board certified. Group, associate or institutional practice. Chief medical resident at Memorial Hospital, Brown University. Fellowship at Wayne State. Available July 1977. D.R. Vemireddy, M.D., 9339 Pickwick Circle West, Taylor, MI 48180.



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Internal Medicine (Cardiology): Available August 1977. Board certified. Desires group or institutional practice. Interested in clinical teaching position. M.D. from Wayne State. Fellowship at Iowa. William S. Sarnat, M.D., 711 Keswick Drive, Iowa City, IA 52240.

Internal Medicine (Cardiology): Hospital or group practice desired. ABIM taken in 1976. Available July 1977. M.D. from Univ. of So. California. Internship and residency at Georgetown. Fellowship at University of Vermont. 31 years old. Michael Schwartz, M.D., 406-A Dalton Drive, Winooski, VT 05404.

Internal Medicine (Cardiology): Available May 1977. Interested in invasive and non-invasive cardiology. Completing fellowship at Cedars—Sinai Medical Center in Los Angeles. M.D. from University of Pittsburgh. Thomas S. Brodie, M.D., 503 No. La Jolla Ave., Los Angeles, CA 90048.

Internal Medicine (Cardiology): Group, associate or institutional practice desired. Board certified. K.P. Channabasappa, M.D., 3241 Pickwick Circle, E #22, Taylor, Michigan 48180.

Internal Medicine (Cardiology): Available July 1977. Degree from University of Manchester, England. Residency at Stamford, CT. Completing fellowship at Nassau County Medical Center. Desires group or associate practice. Charles I. Okonkwo, M.D., 410 Maryland Ave., Staten Island, NY 10305.

Internal Medicine (Gastroenterology): Board certified ABIM. M.D. from NYU. Internship and residency at Boston University Hospital. Fellowship at New Jersey College of Medicine. Available July 1977. 30 years old. Married. Solo, group or associate practice. Resume on file at CSMS. SW-GI.

Internal Medicine (Gastroenterology): Board certified. FLEX. Completing Hutzel Hospital, Detroit, Michigan. Available July 1977. S.K. Singal, M.D., 3737 Beaubien #909, Detroit, MI 48201.

Internal Medicine (Gastroenterology): Board certified. Group or associate practice desired. M.D. from Cornell. Internship and residency at N.Y.-Cornell. Fellowship at University of Pennsylvania. Mark A. Sullivan, M.D., 2834 Midvalle Ave., Philadelphia, PA 19129.

Internal Medicine (Gastroenterology): Prefers multispecialty group. Board certified. 30 years old. Married. M.D. from Upstate Medical School, NY. Completing fellowship at North Carolina Memorial Hospital. Internship and residency at University of Virginia. Keith S. Turner, M.D., 416 Hickory Drive, Chapel Hill, NC 27514.

Internal Medicine (Gastroenterology): Board certified ABIM. Available August 1977. Fellowship at Brooke Army Hospital, San Antonio, TX. Presently on active duty. 32 years old. Married. M.D. from New Jersey College of Medicine. Interned at St. Vincent Hospital, Worcester, MA. James L. Stammer, M.D., 5314 LaCieniga Circle, San Antonio, TX 78233.

Internal Medicine (Gastroenterology): Available late summer 1977. Board certified. Group or associate practice desired. M.D. from George Washington University. Completing fellowship at U.C.L.A. Marc K. Binder, M.D., 20820 Anza Ave., #204, Torrance, CA 90503.

Internal Medicine (Gastroenterology): Available July 1977. Seeks group practice. M.D. from NYU Medical School. Fellowship at St. Luke's Hospital in NYC. 30 years old. Board eligible. Elliot H. Borak, M.D., 505 E. 14th Street, New York, NY 10009.

Internal Medicine (Hematology-Oncology): FLEX. Board eligible. Completing training at Long Island Jewish Hospital. 32 years old. Available July 1977. C.U. Zachariah, M.D., 164-10 84th Avenue, Apt. 4G, Queens, NY 11432.

Internal Medicine (Nephrology): Board certified in IM. Completing fellowship from Albany and Thomas Jefferson Hospitals. M.D. from University of Cincinnati. Interned at NY Medical College. Charles F. Schiffer, M.D., 4 Grant Court, Guilderland, NY 12084.

Internal Medicine (Nephrology): IM with acute and chronic dialysis. Completing fellowship at Mass. General. Available July 1977. Princeton grad. M.D. from Harvard. 28 years old. Group or associate practice in large community. Robert J. Goldstein, M.D., 108 Presidents Lane. Quincy, MA 02169.

Internal Medicine (Oncology): Available July 1977. Board eligible. FLEX. Completing training at Queens Hospital, Jamaica, NY; 33 years old. M.D. from Taipei Medical College, Taiwan. Chia Y. Chou, M.D., 86-31 57th Ave., Elmhurst, NY 11373.

Internal Medicine (Pulmonary): Board certified. Available summer of 1977. Completing fellowship at Bellevue Hospital. M.D. from Boston University. Prefers group or associate practice. 31 years old. Resume on file at CSMS. J.R.S.-Pulmonary.

Internal Medicine (Pulmonary): Presently in US Navy at National Naval Medical Center, Bethesda. ABIM 1973. Desires to do pulmonary consults, intensive respiratory care, fiberoptic bronchoscopy and pulmonary function lab. Available July 1977. Brown graduate. M.D., from Univ. of VA. Internship and residency at Albany Medical Center. John D. Royall, M.D., 9923 Lake Landing Road, Gaithersburg, MD 20760.

Internal Medicine (Pulmonary): Available July 1977. M.D. from Boston University Internship and residency at George Washington University. Fellowship at North Carolina. Group practice desired. Ronald J. Scott, M.D., 420 Overland Drive, Chapel Hill, NC 27514.

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(If no name is listed, contact the Physician Placement Service for more details.)

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Internal Medicine: Illness will require very active internist to discontinue his practice in the Hamden area. Contact CSMS.

Pathology: Opportunity in small community hospital in Central Connecticut. Contact CSMS.

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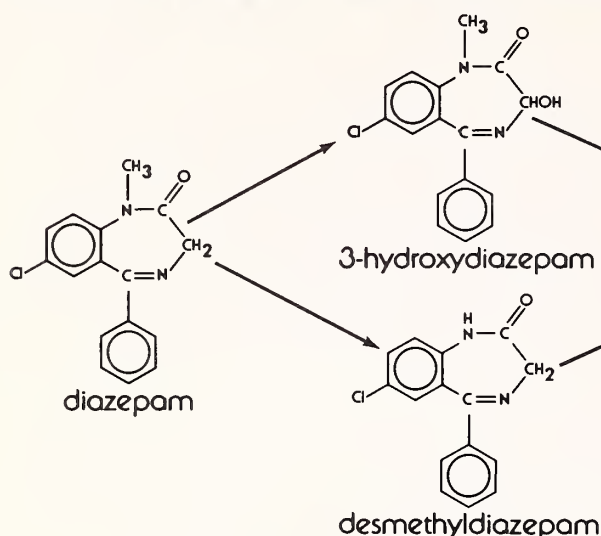
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Rheumatoid Arthritis of the Hand

Stewart H. Harrison, F.R.C.S. (England); F.R.C.S., L.D.S., R.C.S. (Edinburgh)

ABSTRACT—Rheumatoid arthritis is a common disease, and frequently disables and deforms the hands. Reconstructive surgery can relieve pain, correct deformity, and restore function. The capabilities of reconstructive surgery in rheumatoid arthritis have been significantly advanced in the last decade. The author's experience with and contribution to the surgery of the rheumatoid hand is discussed.

Approximately three percent of the female and 1.8 percent of the male population of this country, United Kingdom, are afflicted with Rheumatoid Arthritis, and although many do not progress to disabling handicap in terms of deformity of the hand, nevertheless, their problem is large enough to claim a great deal of our time and attention.

The cardinal signs and symptoms of Rheumatoid Arthritis are:

- 1) Pain
- 2) Swelling
- 3) Limited movement
- 4) Deformity

These lead to disuse atrophy, and frequently set up a chain reaction to deformity unless the chain is interrupted early.

Treatment

The treatment of Rheumatoid Arthritis comes under four headings:

- 1) Symptomatic
- 2) Preventive
- 3) Reconstructive
- 4) Salvage

Symptomatic treatment is by synovectomy. This effectively relieves pain and therefore improves the function of the hand, reducing the disuse atrophy.

Synovitis affects both the tendon sheaths and the synovial lining of the joints, and is classified as follows:

- 1) Acute synovitis
- 2) Proliferative synovitis
- 3) Fibrosing synovitis

MR. STEWART H. HARRISON, Consultant Plastic Surgeon, Wexham Park Hospital; the Mount Vernon Centre for Plastic Surgery, Northwood, England. He is the current President of the British Association of Plastic Surgeons. Mr. Stewart Harrison, F.R.C.S. was the Visiting Professor of Hand Surgery with the Section of Plastic and Reconstructive Surgery, Yale University School of Medicine, on January 19, 1976.

Reprint requests to: Yale University School of Medicine, Department of Surgery (Plastic), 333 Cedar St., New Haven, CT 06510 (Frederick Finseth, M.D.).

Synovectomy is undertaken for the proliferative type in the presence of minimal erosive changes seen radiologically, except where the bulk of tissue is deforming the normal anatomy.

Acute synovitis often remits and may be spontaneously curative, and is therefore not an indication for surgery, or it may progress to the proliferative stage.

Our first report of synovectomy of the MCP joints¹ was a series of cases in which there were gross erosive changes present on X-ray. The result of synovectomy in these cases showed 62.5% recurrence rate. We followed with a trial of 122 selected cases of Rheumatoid Arthritis affecting the proximal interphalangeal joint in which the condition was proliferative, and the swelling did not fully remit.² In these cases, the X-ray changes were absent, or confined to a single pin-head erosion, which was curetted at the time, and frequently cured. At the first follow-up after a year, 22 cases had recurred, and all of these were sero-positive. At the five-year follow-up, 60% had some recurrence, but the majority of these were sero-positive, and many were free from pain. (Figure 1).



Figure 1

A triple curved incision enables access to both sides of the dorsum and also the ventral aspect of the joint. This incision allows three flaps to be elevated as distinct from what is called the "Lazy S", which allows only two.

In many cases, synovial tissue presents between the intrinsic and the extensor tendons, producing a partial Boutonniere Deformity. A mass of proliferative tissue may also extend proximally in the pouch of synovial membrane beneath the extensor tendon, and can erode the extensor tendon, producing a complete Boutonniere Deformity.

Exposure of the anterior aspect of the joint reveals a joint invariably full of proliferative synovial tissue which can obliterate the joint cavity, and extend out

of the joint into the check ligament and along the upper surface of the profundus tendon. Free fluid is often seen, and any nodule in the flexor tendon should be removed, as it will prevent full flexion of the finger.

Flexor Tendon Synovectomy

In the palm, flexor synovectomy relieves compression of the median nerve in the carpal tunnel. It relieves pain from pressure when gripping. It relieves limitation of movement from tendon involvement within a rigid sheath, and therefore increases the range of movement. At the same time, it avoids secondary limitation of joint movement in the proximal interphalangeal joint. (Figures 2-5).



Figure 4

A typical trigger finger is due to a nodule within the tendon sheath.



Figure 2

This is the requisite exposure of the palm for flexor tendon synovectomy.



Figure 5

Half of one flexor tendon with a nodule is seen in situ.



Figure 3

The proliferating synovial tissue surrounds the flexor tendon.

Preventive

Synovectomy of the extensor tendons reduces the incidence of tendon rupture, and is particularly indicated in relationship to the extensor pollicis longus, which is the most frequent tendon to rupture.

Synovial swelling around the head of the ulna gives rise to pain and causes radial deviation of the wrist. This is said to increase the angle of incidence of the extensor tendons, and so promotes ulnar drift. When removing the ulnar bursa, the ulnar styloid should also be removed, otherwise a recurrence is inevitable. This operation is now being done routinely, prior to metacarpophalangeal arthroplasty, in order to correct radial deviation of the wrist, and bring the metacarpals into alignment with the phalanges.

Reconstructive

The commonest tendon in the hand to rupture is the extensor pollicis longus, and next the extensor of the little finger. Rupture of the extensor tendons is

very much more common than rupture of the flexor tendons, and there are probably two causative factors: one is direct involvement of the tendon by synovial proliferative tissue; and the other is attrition by exposed bone, which is a common cause of rupture of the extensor of the little finger.³ (Figures 6-7).

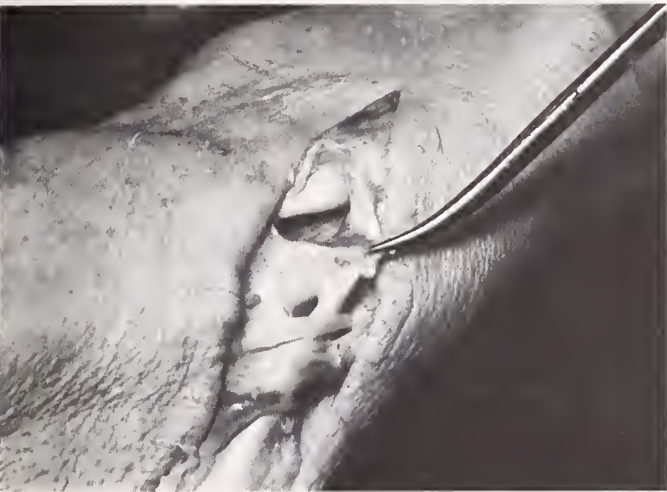


Figure 6

This is a typical rupture of the extensor pollicis.



Figure 7

The repair is seen, using the extensor pollicis brevis as a transplant in the buttonhole operation.

Forty cases were presented to the Heberden Society.⁴ Two cases ruptured subsequent to operation and were repaired successfully later. It is common to see an adduction deformity of the thumb in Rheumatoid Disease, and it is preferable therefore to avoid accentuating this by using the extensor brevis, which lies more radially, and tends to extend the thumb in abduction.

The extensor indicis proprius should be preserved in case it should be required as a transplant for the extensor tendons of the finger should they rupture. It is now our practice to use the extensor pollicis longus as a transplant when all the extensor tendons on the dorsum of the hand have ruptured. Rupture of the

extensor tendons of the fingers are repaired by tendon transplants from the thumb, index, middle or sublimis luxation of the metacarpophalangeal joints is corrected at the same time.

The Thumb

The commonest flexor tendon to rupture is the long flexor tendon of the thumb. This can rupture in one of three places:

- 1) Avulsed from its insertion
- 2) At the level of the metacarpophalangeal joint
- 3) In the carpal tunnel

The tendon rupture is repaired by a tendon graft, but it should be remembered that the first metacarpophalangeal joint is probably affected by the rheumatoid process, and if it is not stabilized at the time of tendon grafting, it will develop a flexion deformity. Stabilization can be effectively performed by using the straight peg.⁵

The first metacarpophalangeal joint is the site of a deformity called the "Z-Deformity", which is similar to a Boutonniere Deformity of the finger in which there is a flexion deformity at the metacarpophalangeal joint, and a compensatory hyperextension deformity of the terminal joint, the disability being greatest in the terminal joint due to limited flexion. Flexion deformity produces a relatively short thumb, and although a short thumb is a disability in an adult, it can be a serious handicap in the rheumatoid patient if there is limited flexion of the index finger, as pinch becomes difficult to perform (Figures 8-9).



Figure 8

This is a typical "Z-Deformity". This deformity should be corrected by the insertion of a straight peg (see Fig. 9) to prevent progressive hyperextension deformity of the terminal joint and to correct the short thumb deformity. This operation takes 15 minutes to perform and has been done on 75 occasions without any complications.

Thumb Carpometacarpal Joint

The wrist is frequently involved in Rheumatoid Arthritis, and involvement of the carpometacarpal joint leads to primary adduction deformity of the thumb. Adduction deformity is classified as follows:

- 1) Primary adduction deformity

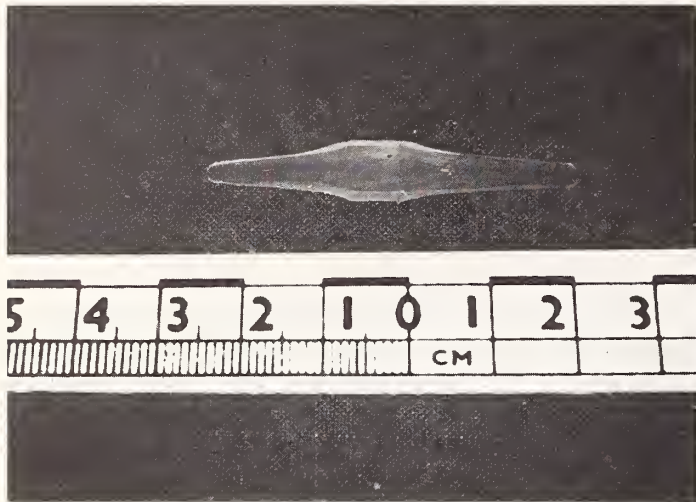


Figure 9

The Harrison-Nicoll intramedullary peg used for thumb metacarpophalangeal arthrodesis.

- 2) Secondary adduction deformity
- 3) Paralytic

Primary adduction deformity is due to involvement of the first carpometacarpal joint. Secondary adduction deformity is where the thumb pursues the retreating fingers in ulnar drift. Paralytic adduction deformity is where the motor branch of the median nerve is involved in carpal tunnel syndrome. (Figure 10).



Figure 10

Paralytic adduction deformity is where the motor branch of the median nerve is involved in carpal tunnel syndrome.

The treatment of primary adduction deformity is by the insertion of an intermetacarpal bone graft from the olecranon, and very often a silastic sheet is inserted into the carpometacarpal joint to prevent fusion. Thirty such cases have been performed with relief of pain and deformity. (Figure 11).⁶

Arthroplasty of the Metacarpophalangeal Joints

Criteria for arthroplasty is:

- 1)Ulnar drift 2)Subluxation 3)Limited extension



Figure 11

Intermetacarpal bone graft for primary thumb adduction deformity.

Figure 12 shows a case in which an excision arthroplasty has been done before correcting the radial deviation of the wrist, and it is apparent that it is



Figure 12

Complication of recurrent deformity following excision arthroplasty of the metacarpophalangeal joints, before correcting the radial deviation of the wrist by ulnar styloidectomy.

impossible to align the fingers to a radially deviated wrist and metacarpals. Therefore, our practice now is to do an ulnar styloidectomy prior to operation, in order to correct the radial deviation of the wrist. It should be mentioned in passing, however, that radial deviation of the wrist is not always due to ulnar styloid involvement, but can be secondary to ulnar drift. Originally, our practice was to do an excision arthroplasty, but although this provides a range of active movement of the fingers of about 40 degrees, it was found that removal of the 1-2 cm of the head of the metacarpal left the patient with a weakened grip. Conventional prostheses e.g. Flatt, Swanson, Niebauer, Calnan, Nicolle, etc. have the advantage of correcting the subluxation and act as spacers.⁷

After operation, the hand is immobilized in plaster of Paris, and subsequently controlled splintage should be maintained for three to six months. (Figure 13).



Figure 13

Dynamic splintage following metacarpophalangeal arthroplasty.

It is important in Rheumatoid Arthritis to take simple measurements of the range of movement of the fingers, and this is routinely done when the patients are seen as out patients, prior to operation, and as a measurement of their progress subsequent to operation. (Figures 14-15).

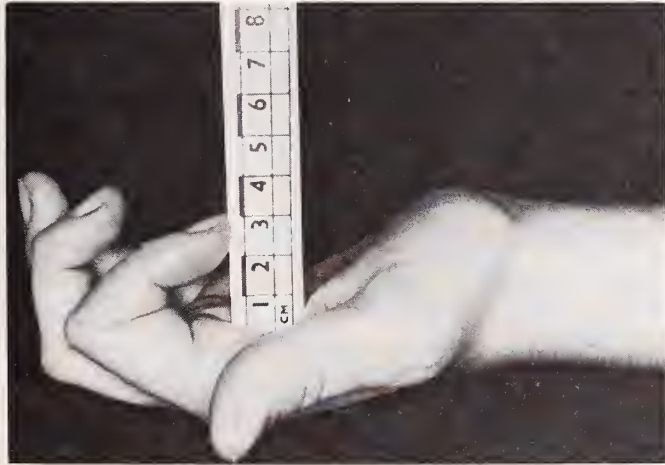


Figure 14

This is the method of taking simple hand measurements.

	RIGHT		LEFT	
	F.D.	E.D.	F.D.	E.D.
INDEX				
MIDDLE				
RING				
LITTLE				
F.D.-FLEXOR DEFICIT-E.D.-EXTENSOR				

Figure 15

The chart method for recording measurements on a die-stamp.



Figure 16

A patient with bilateral hand deformities had the function of the right hand salvaged by simple re-arrangement of the relationship of the thumb and index finger.

Salvage

Figure 16 demonstrates the hands of a patient who had deformities involving both hands. The right hand was a mirror image of the left, as can be seen on the slide. This patient was almost totally disabled, could not look after himself at home, and could not do his job. By simple re-arrangement of the relationship of

the thumb and index finger, this patient was not only able to perform all his domestic functions but was able to return to useful work, and this emphasizes the fact that provided you can preserve or restore the thumb, index, and middle finger relationship these patients are functional and can undertake all their domestic responsibilities.

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A Summary of AMA, Medical and Health News

An administrative law judge has certified to the full Federal Trade Commission the AMA's motion for FTC reconsideration of its restraint of trade complaint. In addition, the FTC administrative law judge has changed the trial date from June 7 to Sept. 7. The FTC complaint, regarding advertising by physicians and medical ethics, was issued against the AMA, the Connecticut State Medical Society and the New Haven Medical Association in December, 1975.

No organization rates higher than the AMA in public credibility, according to a recent Gallup poll. The poll tested the public's belief in communications of all types from government agencies, labor unions, and professional and trade associations. The AMA ranked 6.8 on a ten-point scale, while the average for professional associations was 6.5. The average rating for trade associations was 5.1, for government agencies 5.7, and for labor unions 5.4. In one portion of the poll the public demonstrated its belief that AMA actions are in the public interest by giving the Association a high 6.6 rating. This feeling of trust was supported in another Gallup poll in which 71% of the public said it had a great deal or a fair amount of confidence in physician organizations to propose fair and workable health programs.

At latest count the Federal Trade Commission has issued 48 subpoenas in its restraint of trade investigation

of medical organizations. Included are 11 medical specialty boards and 37 specialty societies. The specialty boards subpoenaed are allergy and immunization, anesthesiology, family practice, internal medicine, nuclear medicine, otolaryngology, pathology, pediatrics, radiology, surgery, and urology.

The FTC was asked to reconsider its complaint of restraint of trade against the AMA and two medical societies regarding advertising by physicians. In a brief filed with the commission, the AMA said its policy book on ethics, *Opinions and Reports of the Judicial Council*, was being revised before the FTC complaint was filed. As a result, the brief said, the AMA is being forced to defend statements that do not even reflect current policy. The FTC complaint was filed in December, 1975, against the Association, the Connecticut State Medical Society and the New Haven Medical Association.

Four medical schools have stated publicly they will refuse federal capitation assistance rather than be forced to accept U.S. citizens from foreign medical schools. The four schools planning to oppose the forced-transfer provision of the new health manpower bill are Indiana U., Yale U., Stanford U., and Wright State U. in Dayton, Ohio.

Calcium and the Kidney: Renal Osteodystrophy and Renal Calculi

(This is the fifth of a series of five articles on calcium metabolism.)

Gregory R. Mundy, M.D., Ernesto M. Canalis, M.D. and Lawrence G. Raisz, M.D.

Recent advances in our knowledge of the metabolism of vitamin D and of the renal handling of calcium and phosphate have resulted in a new look at the mechanisms and management of patients with the complex mixture of metabolic bone disease that occurs in uremia and with the difficult problem of recurrent calcium-containing renal stones.

I. Uremic Osteodystrophy

Bone disease is an invariable accompaniment of chronic renal failure, but its clinical expression is quite variable. Osteomalacia, osteitis fibrosa cystica, osteoporosis, and osteosclerosis can all occur, not only in different patients, but at different times or in different locations in the same patient. Proper management requires the identification of the predominant lesion and an understanding of its pathogenic mechanism (Table 1).¹

1. Osteomalacia

Osteomalacia is common in patients with renal failure who are on diets relatively deficient in vitamin D and living in areas with little sunlight. The frequency with which osteomalacia is reported in renal failure varies not only because of differences in the populations studied, but because different histologic criteria are used in making the diagnosis. The morphologic hallmarks of osteomalacia are wide osteoid seams, with an increased absolute volume of osteoid tissue and a decreased rate of osteoid mineralization. If only the width of the osteoid seam is assessed on bone biopsy, then the diagnosis cannot be made with certainty. Wide osteoid seams may occur in any state of increased bone turnover even if mineralization is not impaired. This can occur in hyperparathyroidism and also in patients given fluoride either therapeutically or because their dialysis fluid is made with fluoridated water. Conversely, patients who have both osteomalacia and osteoporosis will have decreased new bone formation and collagen synthesis and therefore, the osteoid seams may be less wide than expected. Nevertheless, these patients may still show decreased mineralization of that osteoid which is formed. Thus, measurements of mineralization rate using tetracy-

cline labeling help to interpret the osteoid width or amount in bone biopsies.

The osteomalacia of renal failure can have the same clinical features and radiologic findings as that observed in vitamin D deficiency or malabsorption. Decreased mineralized bone mass and occasional pseudofractures are seen in adults, while in children growth is impaired, and there may be ricketic deformities, with radiologic findings of widened epiphyseal plates and cupping of the metaphysis. The major difference between osteomalacia in renal failure and other forms is that the serum phosphate concentration may not be decreased in renal failure. However, in patients with the osteomalacic form of renal osteodystrophy, the elevations in serum phosphate tend to be less marked.

The pathogenesis of osteomalacia in uremia is complex. The major defect is believed to be failure of renal tubular conversion of 25-hydroxy vitamin D (25 OH D) to the dihydroxy form (1,25 (OH)₂D).^{2,3} In chronic renal failure this can occur for two reasons. First, as glomerular filtration rate decreases, phosphate is retained. Increased intracellular phosphate could directly inhibit the renal 1-hydroxylase enzyme. Second, as renal mass is decreased, the cells which contain this enzyme could be lost. In addition to deficient activation of vitamin D, chronic renal failure may impair intestinal function directly so that there is decreased calcium absorption independent of any change in vitamin D metabolism, possibly due to the effects of uremic toxins on the gut.

2. Osteitis Fibrosa Cystica

Progressive renal failure is regularly accompanied by a progressive increase in parathyroid hormone synthesis and secretion. The major factor producing secondary hyperparathyroidism is the hypocalcemic effect of phosphate retention. Increased serum phosphate concentration tends to lower serum calcium concentration by several mechanisms, including inhibition of bone resorption, increased deposition of calcium, and phosphate in bone and soft tissue, and possibly decreased activation of 1,25 (OH)₂D which leads to impaired intestinal absorption of calcium. As renal mass is lost, increasing PTH secretion can maintain fasting serum calcium and phosphate concentration normal until late stages, but only at the expense of parathyroid hyperplasia and some degree of osteitis

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Table 1

FEATURES OF THE BONE DISEASE IN UREMIA

<i>Bone Disease</i>	<i>Histology</i>	<i>Radiologic Features</i>	<i>Pathogenesis</i>
1. Osteomalacia	increased osteoid tissue tissue decreased calcifi- cation front	bone demineralization pseudofractures (rare)	decreased 1,25 (OH) ₂ D due to decreased renal mass, and phos- phate inhibition of 1 OH-ase enzyme.
2. Osteitis fibrosa cystica	increased resorptive surfaces	bone demineralization subperiosteal resorption	PTH increased by hypocalcemia due to high serum phosphate and decreased 1,25 (OH) ₂ D.
3. Osteoporosis	decreased bone mass	bone demineralization vertebral compression	unknown ?heparin? protein deficiency
4. Osteosclerosis	increased bone formation	"rugger jersey spine"	unknown

fibrosa cystica. Pathologically the bone change is similar to that seen in primary hyperparathyroidism. Generalized bone demineralization and subperiosteal resorption of the phalanges are frequently found. "Salt and pepper" mottling of the skull, loss of the lamina dura of the teeth, and cystic lesions or brown tumors of long bones are seen occasionally. Soft tissue calcification is common in chronic renal failure, particularly of the skin and blood vessels. The latter can readily be seen radiologically. Skin mineral deposition may cause severe itching and vascular calcification may be associated with vascular insufficiency and even gangrene. Although secondary hyperparathyroidism usually maintains serum calcium concentrations at or near normal, late in renal disease hypocalcemia may occur. In patients treated with high calcium dialysis and phosphate restriction or in whom renal failure is relieved by transplantation, persistent parathyroid hyperplasia may result in excessive PTH secretion and hypercalcemia can develop. This is because the hyperplastic glands are slow to involute and their secretion is not completely turned off, so that they continue to secrete PTH even at high serum calcium concentrations.⁴

3. Osteoporosis

The decrease in bone mass seen in chronic renal failure may be associated with thin well-mineralized bone trabeculae characteristic of osteoporosis. This change is difficult to recognize radiologically or even histologically in bone which also shows osteomalacia and osteitis fibrosa cystica. Nevertheless, some degree of osteoporosis is often present, particularly in patients on long term maintenance hemodialysis. The pathogenesis of osteoporosis in chronic renal failure is

unknown. Contributory factors could include protein-calorie malnutrition and effects of uremic toxins or chronic acidosis.

4. Osteosclerosis

Occasional patients with chronic renal failure show increased radiologic density of some bones, particularly the vertebrae. The appearance of bands of osteosclerosis adjacent to the disc space with less dense bone in the center of the vertebrae produces a pattern termed the "rugger jersey spine," but this is relatively rare. The cause of osteosclerosis in renal failure is unknown. Contributory factors could be the increase in serum phosphate concentration, which can promote both bone matrix formation and mineralization and the accumulation of excess fluoride in the bone in patients dialyzed with fluoridated water. It is also possible that some as yet unidentified vitamin D metabolite or other bone growth factor may accumulate in renal failure and stimulate new bone formation.

Serum Calcium and Phosphate Concentrations in Chronic Renal Disease

As noted above, patients with early or moderate renal failure often show complete compensation with normal fasting serum calcium and phosphate concentration. Serum calcium usually decreases and phosphate increases in endstage renal failure. Patients with osteomalacia tend to show lower serum calcium and phosphate concentrations than patients in whom the primary lesion is secondary hyperparathyroidism with osteitis fibrosa cystica. As noted above, treatment designed to raise serum calcium and lower serum phosphate can lead to hypercalcemia, as can successful renal transplantation. If hypercalcemia persists

after renal transplantation for many months, it is possible that the glands are no longer simply hyperplastic and showing slow involution, but have become autonomous. If the term "tertiary hyperparathyroidism" is to be used at all, it should be reserved for those patients who actually have autonomous parathyroid adenomas developing on a background of secondary hyperparathyroidism, and not for those in whom parathyroid hyperplasia involutes slowly after transplantation.

Management of Uremic Osteodystrophy

The only procedure which can reverse the changes of uremic osteodystrophy reliably is renal homotransplantation. Even here, as noted above, hypercalcemia may be produced, and in addition, another bone lesion, aseptic necrosis, particularly of the femoral heads, is frequently observed. The mechanism of aseptic necrosis is not clear. The use of glucocorticoids after transplantation has been implicated, but some patients develop the lesion without steroids. Occasionally patients show aseptic necrosis during the development of uremic osteodystrophy before transplantation.

Transplantation is not possible in the majority of patients with chronic renal failure and current therapeutic approaches are therefore based on attempts to reverse the pathogenetic sequence of events which has caused the particular form of bone disease in that patient. The indications for therapy in uremic osteodystrophy include: 1.) serum phosphate concentration greater than 5 mg/100 ml, 2.) bone pain, 3.) marked elevation in serum alkaline phosphatase, which can be an indicator of excessive osteoblastic activity, 4.) radiologic changes including bone demineralization, subperiosteal resorption, cysts, and pseudo-fractures and, 5.) histologic evidence of bone disease on bone biopsy.

The major aim of therapy is to reverse or prevent osteopenia and soft tissue calcification. Various therapeutic measures are currently under intense study and no optimum regimen for particular form of bone disease has yet been defined. Some of the useful therapeutic measures include:

1. Diet

It is desirable to decrease phosphate intake and increase calcium intake. Dietary phosphate restriction is of limited use, partly because foods rich in phosphate are also rich in calcium. It is possible, however, to reduce phosphate intake in the diet and supplement with oral calcium in the form of calcium lactate or gluconate to provide 800—1,000 mg per day of calcium. This supplemental calcium will not be absorbed well unless some active form of vitamin D is also administered.

2. Aluminum Hydroxide

Aluminum Hydroxide binds phosphate and prevents its absorption. Thus, it can lower serum phosphate concentration. The therapy is difficult to control partly because it is difficult to obtain consistent compliance. Thus in some patients there will be little effect, while in others, excessive phosphate depletion can occur. Therefore, serum phosphate concentration must be carefully monitored. If phosphate is decreased to abnormally low values, the calcium-phosphate product will not be sufficient for mineralization and osteomalacia may occur; moreover, hypercalcemia may develop.

3. Vitamin D

Vitamin D can be used to treat both osteomalacia and osteitis fibrosa cystica in chronic renal failure. In fact, treatment with active metabolites of vitamin D has been reported to be more effective in reducing secondary hyperparathyroidism than in restoring defective mineralization. Unfortunately, the active metabolites, 25 OH D and 1,25 (OH)₂D, are not yet commercially available. Currently, vitamin D₂ or vitamin D₃ can be used, but the most commonly used form is dihydrotachysterol (DHT) in large doses of 0.4 to 0.8 mg/day. DHT was originally selected empirically, but its effect may be related to the fact that it does not require 1-hydroxylation for maximal activity. While the 1,25 metabolite seems the most logical one to use in renal osteodystrophy, and has been found effective in very small doses, somewhat larger doses of 25 OH D are also quite effective.⁵ Whatever form of vitamin D is used, the serum calcium must be carefully monitored and hypercalcemia avoided.

4. Dialysis

Uremic osteodystrophy can be prevented or reversed in many patients by the use of frequent dialysis with a high calcium concentration in the bath fluid (7 to 8 mg/100 ml). Using high calcium dialysate and a low phosphate intake with aluminum hydroxide gel between dialysis, it is possible to maintain the serum calcium concentration and prevent secondary hyperparathyroidism. Such therapy may be preferable to the use of DHT or other vitamin D metabolites because it is easier to avoid prolonged hypercalcemia. However, transient hypercalcemia can occur in patients treated with high calcium dialysis and phosphate binders; and this may be helpful in producing involution of hyperplastic parathyroid glands.

5. Parathyroidectomy

Sub-total parathyroidectomy is only rarely indicated in patients with chronic renal failure. Prior to renal transplantation the major indication is intractable symptomatic secondary hyperparathyroidism with

bone pain, fractures, or increased calcium phosphate deposition in the skin and vessels causing severe itching or vascular insufficiency. However, a vigorous trial of medical therapy should be carried out before recommending surgery. After transplantation, hypercalcemia is the major indication for parathyroidectomy, but this can also be treated medically and will often resolve. Patients who cannot be controlled medically in whom hypercalcemia persists for six months or more, are often subjected to sub-total parathyroidectomy.

The foregoing outline of medical and surgical management in uremic osteodystrophy is currently undergoing revision as we learn more about the use of active vitamin D metabolites, and as the management of patients on chronic dialysis and after renal transplantation is refined. Frequent monitoring of serum calcium, phosphate and alkaline phosphatase concentrations; and the use of bone biopsies, bone density measurements using photon beam absorptiometry and measurements of immunoassayable PTH are not only useful in the management of these patients, but also help to assess the usefulness of new therapeutic regimens.

The Problem of Recurrent Calcium-Containing Renal Stones

Calcium-containing renal stones comprise about 70% of all cases of recurrent nephrolithiasis in this country. Recent advances in our knowledge of mineral metabolism have led to new concepts of the pathogenesis of recurrent calcium nephrolithiasis, upon which a more rational approach to the diagnosis and therapy can be based.

Most patients with recurrent calcium-containing stones have normal oxalate, urate, and cystine excretion. However, it is important to check for hyperoxaluria or hyperuricosuria since these will enhance the formation of calcium-containing stones and can be treated. Hyperoxaluria can occasionally occur as an autosomal recessive congenital disorder which leads to early death from renal failure. In adults it may be secondary to ileal disease, vitamin B₆ deficiency or occur after methoxyfluorane anesthesia. Hyperuricosuria may occur with or without hyperuricemia. In many patients it appears to be due to increased urate intake rather than increased production. Recent studies have shown that urate crystals enhance the formation and growth of calcium oxalate and phosphate crystals.^{6,7}

On the average, urinary excretion of calcium is increased in patients with recurrent calcium-containing stones. It is difficult to separate those with and without hypercalciuria because there is considerable overlap between stone formers and non-stone

formers, and because there are still no universally accepted criteria for normal urine calcium excretion. A conservative upper limit might be 200 mg or urinary calcium per 24 hours in females and 250 mg in males. However, many individuals without renal stones will have higher urinary calcium, particularly on high calcium intakes. Measurement of urinary calcium excretion both fasting and after oral calcium loads can help to define hypercalciuria more precisely. Urinary calcium is usually less than 110 mg per gram of urinary creatinine in normal fasting subjects and less than 170 mg per gram of creatinine in the urine collected in the four hours following the ingestion of one gram of calcium. Many patients with recurrent calcium-containing renal stones show urinary calcium excretion which exceeds one of these limits and have normal serum calcium concentration. Among these patients with normocalcemic hypercalciuria, some may have renal tubular acidosis, vitamin D intoxication, sarcoidosis, Cushing's Syndrome, or "normocalcemic" hyperparathyroidism. However, the majority have no obvious cause and are diagnosed as having "Idiopathic Hypercalciuria."

Nordin et al.⁸ and Pak et al.⁹ have suggested that patients with idiopathic hypercalciuria can be subdivided according to pathogenic mechanism into a group with increased intestinal calcium absorption or "absorptive hypercalciuria" and another with a renal leak of calcium or "renal hypercalciuria." They have used a third term "resorptive hypercalciuria," to designate those patients with primary hyperparathyroidism, excess bone resorption and resultant hypercalciuria and renal stone formation. Pak has devised a test to distinguish among these three groups based on measurements of calcium and cyclic AMP excretion before and after an oral calcium load. The results of this and other diagnostic tests in the three types of hypercalciuric patients are summarized in Table 2. Phosphate measurements are not particularly helpful in distinguishing these three groups since all can show low serum phosphate concentration and decreased tubular re-absorption of phosphate. However, in earlier studies it was possible to separate hyperparathyroidism from idiopathic hypercalciuria in many patients because the hyperparathyroid patients showed persistent low tubular reabsorption of phosphate after an intravenous calcium load, while the non-hyperparathyroid patients showed a marked increase in tubular reabsorption of phosphate when intravenous calcium was given and their endogenous parathyroid hormone secretion was suppressed.

Recently Coe, Lemann, and others¹⁰, have postulated that the mechanism of increased calcium absorption in idiopathic hypercalciuria is increased

Table 2
CALCIUM LOADING TEST IN HYPERCALCIURIA
(Pak et al., N.E.J.M. 292:497, 1974)
Major Mechanism of Increased Calcium Excretion in the Urine

	<i>Renal</i>	<i>Absorptive</i>	<i>Resorptive Primary Hyperparathyroidism</i>
Fasting Urine			
calcium excretion	increased	normal	increased
cyclic AMP excretion	increased	normal	increased
After 1.0 gm Calcium Orally			
calcium excretion	increased	increased	increased
cyclic AMP excretion	normal	normal	increased
Serum Calcium Concentration	normal	normal	increased
Serum PTH Concentration	normal/high	normal	normal/high

activation of vitamin D. If a phosphate leak is a primary defect in these patients, then this could result in low renal tubular cell phosphate concentration and stimulate 1-hydroxylation of vitamin D. Even if the primary mechanism were a calcium leak, 1-hydroxylation might be stimulated indirectly since loss of calcium would produce secondary hyperparathyroidism and this in turn would decrease tubular reabsorption of phosphate and lower renal cell phosphate.

Management of Patients with Recurrent Calcium Stones

Calcium intake should probably be restricted in all patients, even if they do not have hypercalciuria. High fluid intake is usually recommended, but seldom achieved. It is advisable to avoid fluid restriction, particularly at night when patients are often excreting a concentrated urine. High uric acid excretion can be reduced with allopurinol which blocks uric acid synthesis. A separation of normocalciuric patients and those with hypercalciuria of the absorptive, renal, or resorptive type may allow a more rational approach to therapy. Those with resorptive hypercalciuria and hyperparathyroidism can be cured surgically. Patients who absorb excess calcium in the diet should theoretically respond best to phosphate therapy if the pathogenic mechanism described above in which low phosphate increases activation of vitamin D is correct. Cellulose phosphate will also block calcium absorption in the intestine and should be effective in such patients.¹¹ Those patients who are considered normocalciuric on the basis of 24-hour urine calcium excretion, but show increased excretion after oral calcium load, may also be treated as absorptive hypercalciurics. Patients with renal hypercalciuria should respond to thiazides which stimulate distal tubular

reabsorption of calcium.⁶ This treatment will not only reduce urinary calcium excretion, but will correct the secondary hyperparathyroidism produced by calcium loss. The reduction in parathyroid hormone secretion may account for the observation that thiazide treatment can also decrease intestinal absorption of calcium.

While it may be possible to select initial therapy on the basis of the foregoing considerations, we do not have enough data to know what the best long term management of recurrent calcium stones will be. Whether thiazides or oral phosphate are preferable will depend on a much more extensive analysis of long term patient compliance and toxicity as well as efficacy.

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Spontaneous Pneumothorax as a Presenting Feature of Primary Lung Carcinoma

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ABSTRACT—Most commonly, spontaneous pneumothorax occurs secondary to benign pathological conditions. The occurrence of spontaneous pneumothorax in association with metastatic sarcoma has been well documented in the literature. Spontaneous pneumothorax occurring as the first presenting feature in primary carcinoma of the lung has been documented in two series, totalling seven cases. We would like to present two new cases and review the seven cases previously presented in the literature. We recommend that patients of the group at risk for carcinoma of the lung presenting with spontaneous pneumothorax, especially in association with cystic bullous disease, should be followed closely with serial chest x-rays and sputum cytology in order to detect early lung cancer which may have presented initially as spontaneous pneumothorax.

Most commonly, spontaneous pneumothorax occurs secondary to benign pathological conditions. In young males of the third and fourth decades¹⁻³ the commonest cause is rupture of a sub-pleural bleb, usually in the upper lobe. West⁴ points out that in man, by adopting the upright posture, the apex of the lung is subjected to much larger expanding stresses than the rest of the lung and the resulting weight distribution and decreased blood supply of the apex of the upper lobes predisposes to spontaneous pneumothorax, especially in tall thin males.

Honeycombing of the lungs is also associated with a higher incidence of spontaneous pneumothorax.^{5, 6} e.g., eosinophilic granuloma (histiocytosis X),⁷ scleroderma, diffuse interstitial fibrosis,⁹ certain pneumoconioses,¹⁰ and rarely in Marfan's syndrome, tuberous sclerosis, familial fibrocystic pulmonary dysplasia,¹¹ xanthomatosis, biliary cirrhosis and endometriosis.

In elderly patients, Green¹² showed a 10 percent incidence of spontaneous pneumothorax in association with chronic bronchitis and emphysema. In

COPD, such as chronic bronchitis and emphysema, and also in conditions like bronchiectasis, tuberculosis or silicosis, the bullous cavities are usually small with very thin walls and more numerous and usually the more active basal portions of the lungs are involved. In the series by Carr et al,¹³ spontaneous pneumothorax was not found to be common in patients with COPD. 78 percent of patients with a first presentation and 87 percent of patients with recurrent pneumothorax had no history of COPD. In reviewing 22,000 patients with COPD over a 10 year period, Dines et al,¹⁴ found only 95 spontaneous pneumothoraces, and incidence of 1:231.

The occurrence of spontaneous pneumothorax in metastatic sarcoma of the lung has been well described.^{3, 4, 5, 6, 15} In contrast, the occurrence of spontaneous pneumothorax in primary malignant disease has been documented in two series, one by Heimlich²⁰ in 1955 and the other by Dines et al¹⁹ in 1973. Heimlich described 3 cases where spontaneous pneumothorax was the first presenting finding of primary carcinoma of the lung. Dines et al¹⁹ described 4 cases where spontaneous pneumothorax occurred as the first presentation of primary carcinoma of the lung and 6 cases (in the same series) where spontaneous pneumothorax occurred in association with metastatic sarcoma.

Two cases were seen at the Waterbury Hospital Health Center in which the patients presented with spontaneous pneumothorax and were treated as such with thoracostomy tube drainage. Because of the complication in Case I and failure of the air leak to seal in Case II, both cases were operated on, and in both cases, surprisingly, primary carcinoma of the lung was found.

Case I

A 30-year-old white female was admitted with a five day history of sudden onset of right sided chest pain and shortness of breath, both of which progressively worsened. There was radiation of the pain to the right scapula. A chest x-ray showed a right sided pneumothorax (Photo I). The patient was treated with thoracostomy tube drainage and the reinflated chest x-ray showed a soft tissue density over the anterior end of the first rib was suspicious of a lung lesion. A chest x-ray six days later showed an irregular and somewhat triangular infiltrate at the level of the right first rib possibly with two small cavities. This was considered to be an inflammatory process occurring in apical bullous disease. The chest tube was removed on the sixth day, and the patient sent home

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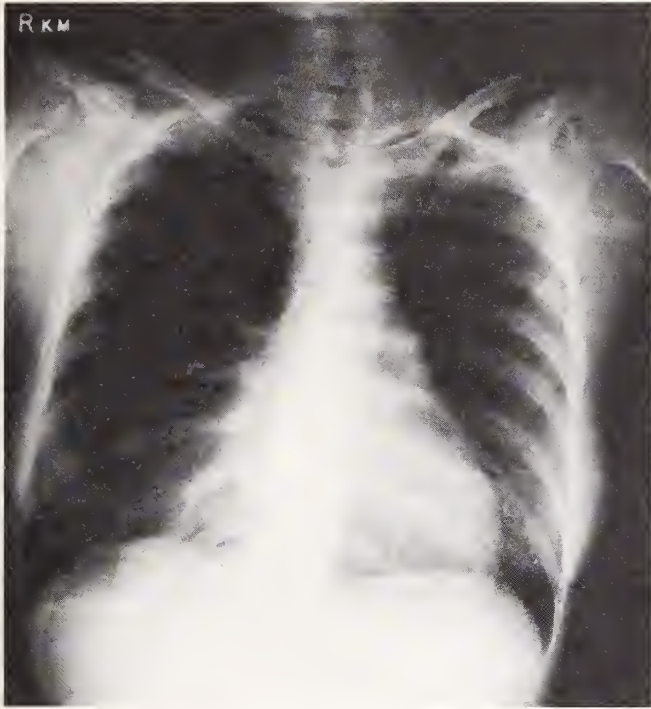


PHOTO I

Rt. Sided pneumothorax present.

on the seventh day after admission, to be followed on the outside with serial chest x-rays.

Sixty-four days later, the patient complained of right sided chest pain and a chest x-ray showed a 7 x 6 cm cavity (Photo II) in the right apex with thick walls and an air fluid level. This was considered to be fluid in cystic areas, noted on previous films, which had increased in size. The patient was afebrile with a white blood count of 6.1×10^3 , $7/NS = 55/7$.

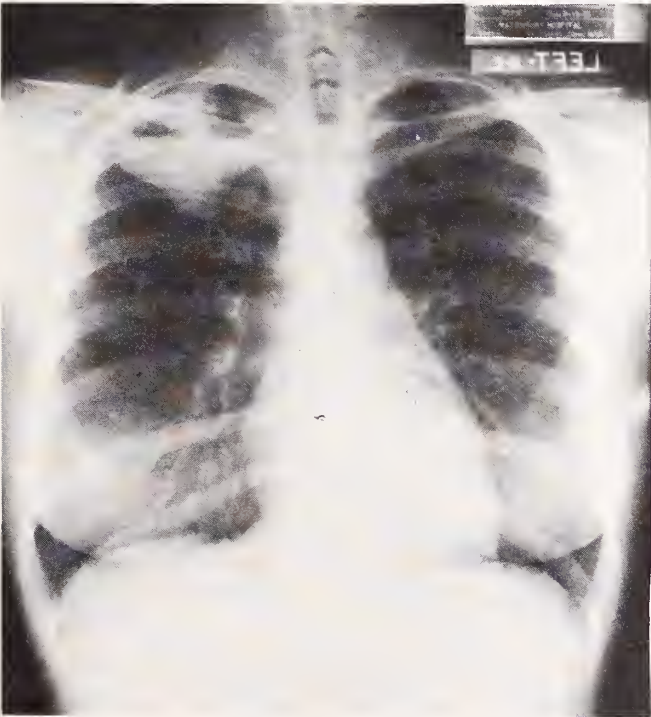


PHOTO II

Cavity with air fluid level present.

Four days after the second hospital admission, the patient had a right thoractomy and a large necrotic area of the right upper lobe (apical segment) with cystic bullous disease was noted. There was

also a hard mass, 2 cms in diameter, which felt "suspicious" on palpation. A right upper lobectomy was done. The patient's post-operative hospital course was uneventful. Chest tubes were removed on the fifth postoperative day and the patient discharged on the eleventh postoperative day.

Pathology Report

Confirmed the 2 cm firm area in the apical segment of slightly lighter pinkish-tan tissue than the surrounding lung tissue. Histological appearance (Photo III) of the mass was a poorly differentiated adenocarcinoma. No metastatic disease was seen in the hilar lymph nodes included in the specimen.

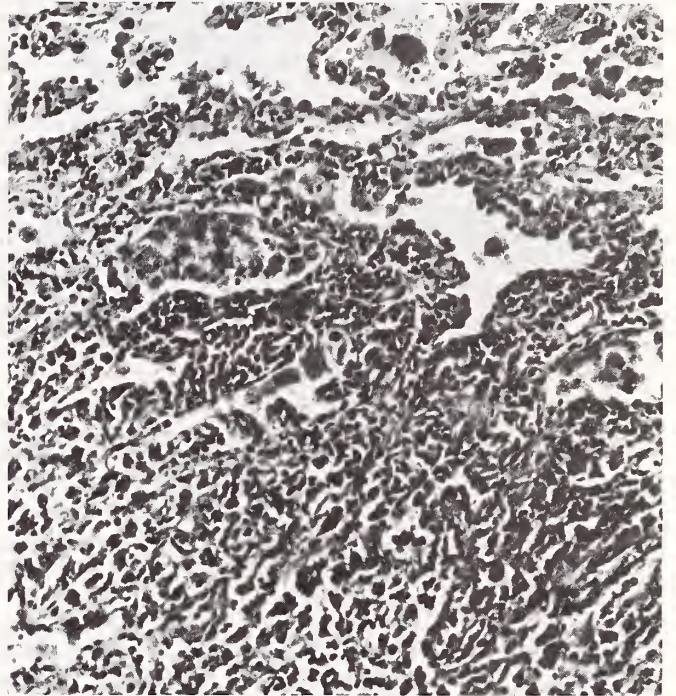


PHOTO III

Pathology slide shows adenocarcinoma arising from the wall of emphysematous bleb.

The patient was fully worked up to rule out a primary cancer elsewhere with upper G.I. series, B.E., IVP, oral cholecystogram; breast, thyroid and pancreatic studies with negative results.

This patient had been a smoker for 18 years (since age 12), smoking two packages of cigarettes per day.

Case II

A 36-year-old white male admitted with right sided chest pain of sudden onset and shortness of breath, blood pressure 130/90, $P=80$, $R=30/\text{min}$. Decreased breath sounds were heard on the right side with hyperresonance to percussion. Chest x-rays (Photo IV) showed a 50 percent right sided pneumothorax. Thoracostomy drainage using an Emerson suction through the right second intercostal space, MCL, was instituted. Four days later the chest tube was removed after the air leak had apparently stopped for 48 hours. Twelve hours later, the patient complained of severe left sided chest pain and a chest x-ray showed complete collapse of the right lung with mediastinal shift to the left. On reviewing the x-ray, bilateral apical bullae were seen. Nine days after admission, the patient had a right thoracotomy with wedge resection of the right apical bullae.

Pathology Report

Evidence of markedly thickened pleura by dense fibrous and hyalinized tissue showing evidence of calcification. In the vicinity of this thickened pleura which forms a bleb, there is evidence of malignant tumor, mostly presenting as a large cell undifferentiated



PHOTO IV
Chest x-ray shows right sided pneumothorax.

pattern (Photo V), but which in some areas shows some adenocarcinomatous differentiation. In other areas, the tumor appears very bizarre and has giant cell features. The tumor appears to be arising in the wall of the bleb. It superficially infiltrates the surrounding pulmonary tissue but does not appear to be present on the pleural



PHOTO V
Adenocarcinoma arising from emphysematous bleb.

surface. Conclusion: Adenocarcinoma, poorly differentiated, arising in the wall of a pulmonary bleb.

Fourteen days after admission, the patient developed an asymptomatic left sided pneumothorax with almost complete collapse of the left lung. This was treated by thoracostomy tube drainage and the chest tube removed on the 27th day post admission.

Twenty days post admission, a right thoracotomy with lobectomy was carried out.

Pathology Report

No definite recognizable tumor present in lung. Many sections of the remaining apex and surrounding areas were taken and all were negative for malignancy. The peribronchial nodes were also negative for malignancy.

This patient had been a smoker for 20 years (since age 17) smoking one to one and a half packages of cigarettes per day.

Discussion

The mechanism for the development of spontaneous pneumothorax in primary carcinoma of the lung may be: (1) Direct invasion of the pleura by the neoplasm or (2) since most of these patients have COPD, rupture of a distended bullous distal to the tumor-caused obstruction may occur. In contrast, idiopathic spontaneous pneumothorax in young people is attributed to the rupture of a subpleural bleb without evidence of 1 and 2 mentioned above.

Although rare, spontaneous pneumothorax occurring in patients of the cancer age group or those at higher risk should be followed with serial chest x-rays and sputum cytology. In the event that the spontaneous pneumothorax was secondary to a neoplasm it could be detected early and surgical cure attempted. The occurrence of spontaneous pneumothorax does not preclude resection in cases of solitary nodules, except for spontaneous hydropneumothorax with a thoracentesis specimen showing a positive sputum cytology and, of course, diffuse pulmonary and hilar adenopathy with radiation therapy may be of value.

Recurrent spontaneous pneumothoraces that fail to stop leaking and localized recurrent lung infection (cystic or diffuse in a segment or portion of a lobe) should all arouse suspicion of neoplasm.

In congenital cystic bullous disease, it has been noted by Korol, Goldstein, and many case reports, that there is an increased incidence of bronchogenic carcinoma. There is also an increased incidence of spontaneous pneumothorax in congenital cystic bullous disease and as such, it is always advisable to bear these observations into consideration.

Conclusion

Spontaneous pneumothorax occurring as the presenting feature of primary carcinoma of the lung is a rare occurrence. However, it should be considered when spontaneous pneumothorax occurs in: (a) patients of the group at higher risk for lung cancer; (b) when there is a persistent air leak after adequate tube thoracostomy drainage; or (c) when recurrent infection occurs in a segment or part of the lung. These patients should be followed closely with sputum cytology and chest x-rays.

Both patients presented in this paper would fall in the higher risk group, since both started smoking at an early age, i.e., 12 years of age for Case I and 17 years of age for Case II.

Sex Age, Yr.	Time Relationship	Neoplasm Type	Primary	X-ray Appearance	Treatment	Follow-up
DINES ↑ M:74 M:56 M:60 F:55 ↓	Same Time	Adeno- carcinoma	Lung	Hydropneumothorax Mass RUL	Radiation No chest tube	Died, 2 mo.
	Same Time	Small Cell, Bronchogenic Grade 4	Lung LLL	Mass LLL, Large pneumothorax, left chest	Chest tube (No expansion)	Died, 5 weeks
	Same Time	Adeno- carcinoma	Lung RLL	Mass RLL, Rt. Hydropneumothorax	Chest tube (No expansion) Radiation	Died, 1 mo.
	Same Time	Metastatic carcinoma cells pleural fluid	Presumed Lung	Hydropneumothorax Left	Chest tube Radiation	Lost
HEIMLICH ↑ M:45 M:53 M:51 ↓	Same Time	Squamous cell carcinoma RUL	Lung RUL	Rt. pneumothorax	Rt. pneumonectomy	At 24 months, patient asymptomatic with no evidence of recurrence of the carcinoma.
	Same Time	Undiff. cell ca. with pleural met.	Rt. Lung	Rt. pneumothorax	Chest tube drainage	Died, 4½ mo.
	5 months later	Adeno- carcinoma	Lung RLL	Rt. pneumothorax	Chest tube drainage	Died, 2 mo.
YUUF, et al. ↑ M:37 F:30 ↓	Same Time	Adeno- carcinoma	Lung RUL	Rt. pneumothorax	Chest tube drainage followed by thoractomy and Rt. upper lobectomy	2 month follow up no evidence of metastasis
	Same Time	Adeno- carcinoma	Lung RUL	Rt. pneumothorax	Chest tube drainage Rt. thoracotomy with Rt. upper lobectomy post-op radiation	4 month follow up patient - no evidence of metastasis

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Premature Ejaculation

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ABSTRACT—Premature Ejaculation is the most common male sexual dysfunction. Etiologically, the male has not learned to prolong the time from intromission until ejaculation. The common dynamic is that increasing sexual frustration may be experienced by the female causing him to withdraw from the sexual relationship. In sexual therapy, regular frequent ejaculation is encouraged along with use of the squeeze technique. In addition, the coital positions with either the male supine or on his side are considered best.

Premature Ejaculation

Premature ejaculation is the most common male sexual difficulty found in our society. In one sense, it has become a sexual difficulty as a result of either partner "watching the clock".

Definition

There is a small group of males that will ejaculate either during foreplay or as soon as their genitals are touched. This is fortunately only a small group of individuals, and the diagnosis of premature ejaculation is readily obvious. A majority of males diagnosed as premature ejaculators are those that ejaculate either during attempted penetration of the penis into the vagina, or during the first few pelvic thrusts. Certain urological services have defined a male as a premature ejaculator if he ejaculates in less than sixty seconds of intercourse. This is a very clock oriented approach, and implies that if a male is able to have intercourse for sixty-one seconds, or more, he does not have premature ejaculation. This we do not agree with. At the other end of the spectrum may be a male who is able to have intercourse for approximately ten minutes; and yet his female partner may state that "if only he could hold out for another minute", she is sure that she would have an orgasm. In one sense, if it was easier for her to have an orgasm he would not be considered a premature ejaculator. To try to settle this moot point, some research has been reported which suggests that a female's sexual increment, or buildup, increases rapidly up to a five minute mark of intercourse, and after that, although there continues to be a buildup, the rate of rise is much smaller. In essence, the approximate five minutes time interval is used as a

cut-off point, and if the male ejaculates before that, he is treated as a premature ejaculator. If a female requires considerably more time to have an orgasm, efforts are made to help her experience an orgasm quicker.

Etiology

What causes so many males to be troubled by premature ejaculation? Many older males have had their first sexual experiences with prostitutes. Since prostitutes are capitalists, and they get paid when the male ejaculates, they usually encourage the male to ejaculate quickly. If a male's first series of sexual experiences has been with a prostitute, and she has, indeed, encouraged ejaculation, it seems entirely plausible that the programming effect is occurring, and quick ejaculation in subsequent relationships may be the norm. Also, couples that have used coitus interruptus as a primary means of contraception may have found that if the female was worried about whether the male would withdraw in time, she may not have allowed herself to think and feel sexually; while, at the same time, there may have been very little need for the male to *learn about postponing his own ejaculation*.

The process of masturbation may also be an important factor if the male, as many do, stimulates himself with the *purpose being* to ejaculate as quickly as possible. It should be thoroughly emphasized that it is not the behavior of masturbation which may contribute to premature ejaculation, but it is the process of masturbation, with its emphasis on speed, that may predispose the male to premature ejaculation.

Another common etiologic factor in premature ejaculation may be stress. In these situations, stress will produce only a situational or periodic premature ejaculation, but if the stress is of long standing duration—either from feelings about self, partner, job, or finances—it may contribute to long term premature ejaculation.

Dynamics

If the male feels it is very important to please his partner, and to "perform" properly, he may become extremely nervous, anxious, or tense. If the female does not receive sexual satisfaction that he feels she should have, he may respond to his nervousness and anxiety by ejaculating quickly. This is particularly true if the male feels that his partner must have an orgasm each and every time to enjoy sex and be satisfied. If the female does not find intercourse particularly enjoyable or satisfying, she may give the male

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verbal or nonverbal messages about her lack of satisfaction. This, in effect, may say to the male “hurry up and get it over with” or it may keep the male treadmill trying harder and harder.

If, during the early years of a marital relationship, a male has been troubled with premature ejaculation; and if the female has not had much sexual experience with other people, she may be convinced that with patience, love, and understanding, the problem will be resolved. Literally, as the years pass her frustration will increase, and, as it does, the female will send messages either verbally or nonverbally to the male that he is inadequate. For self preservation, the male may withdraw sexually, and there will be decreased sexual contact. What frequently happens is that the male who has little control over his ejaculation, when he is ejaculating one to two times per week, will have virtually no control over his ejaculation when the frequency is decreased to one time per month. This then increases his premature ejaculation, which in turn increases her frustration, and a vicious cycle is set up which can be very destructive to the couple. At other times, in an effort to combat the difficulty, a male may start fantasizing some non-sexual material during intercourse as a way of distracting himself and of taking his mind completely off of sex. If this doesn't work, the male may bite the inside of his lip or mouth to further decrease the pleasurable sexual sensations. At times, this blocking phenomenon can be so successful that the male not only loses his need to ejaculate, but also his erection, and this may be the crowning blow to the already deteriorated sexual relationship. At this point in time, the female may wonder if she is O.K. sexually and demand verbally and non-verbally that the male function properly, and “do his job”. As the pressure builds up on the male to get an erection, the fear increases, which further blocks his ability to get an erection, and the vicious cycle continues.

In other instances, the female describes a saw-tooth pattern where because of the male's premature ejaculation, she has been stimulated to a point, and then been left “just hanging”. If this just hanging phenomenon continues for a long period of time—perhaps years—the female may cope with this by gradually not letting herself get as sexually stimulated. In due time, she may present in the physician's office saying that she does not feel anything during intercourse, and if she is erroneously labeled “frigid”, much damage will be done.

Treatment

Treatment of the “couple” with premature ejaculation consists of isolating those stress-producing factors in the relationship and helping a couple to

minimize them. This may be where the counselor's greatest skill will be required, for many times they are very subtle. If, for example, the premature ejaculation is of recent onset, or is present with certain female partners and not with others, it should be fairly easy to isolate. But in premature ejaculation of long term duration, it may be harder to isolate.

In the sexual area, the three factors that are most effective in curing premature ejaculation are: 1) regular, frequent ejaculation, 2) use of the squeeze technique, and, 3) the male either being on the bottom, or in the side to side position in intercourse.

Regular, frequent ejaculations in themselves will help postpone subsequent ejaculations. For many males we will recommend ejaculating three to four times per week, either by self masturbation, partner manipulation, oral sex, or intercourse. In the past, many of the couples with premature ejaculation have coped with the difficulty by having sex less often, which just contributes to the difficulty. By increasing the frequency of ejaculation, it is a positive move toward teaching the male how to control and postpone ejaculation. If the male is ejaculating by masturbation, we strongly encourage him to postpone and delay the process as much as possible by the “stop-start” technique. This consists of automanipulation almost to orgasm—then stop. When the arousal returns to baseline, automanipulation is again commenced.

The squeeze technique is a process whereby the female masturbates the male almost to the point of ejaculation; when the male feels that he is very close to ejaculation he tells the female to apply the squeeze. She does this by placing her two thumbs over the frenulum at the base of the glans penis and by placing her index fingers on the top of the glans penis just distal to the corona ridge, while her middle fingers are proximal to the corona. By squeezing firmly for approximately ten seconds, the male will not ejaculate, and will also lose about 30% of his erection. As she brings him back almost to the point of ejaculation again, the squeeze technique is repeated, and the third time he is allowed to ejaculate. The squeeze technique, like any other skill, is learned, and takes practice. As a couple gets better at it, it will work, and, in time, both the male and female will have the self-confidence that he will not ejaculate quickly. This, in turn, will allow the female to start feeling more sexually, and will remove for the male that source of stress and frustration caused by the premature ejaculation. The pressure of the squeeze on the erect penis does not hurt, but this point may have to be emphasized several times to both the male and female. Immediately prior to ejaculation, the penis is virtually insensitive to pain from pressure. This technique

should be employed several times per week for a minimum of six months.

Coital position is also important. When the male is in the superior position during intercourse, he has very little control over his ejaculation. Whereas, when the male is on the bottom during intercourse or in a side to side position, his ejaculatory control is defi-

nately increased. To achieve this result may require considerable discussion with the couple on the part of the counselor, for to take a couple that has been used to having intercourse in the male superior position for a number of years, and suddenly change that may radically upset some of their socially described prerequisites for "good sex."

Near-Drowning

Norman L. Fine, M.D.

Introduction

In the past few years clinical concepts regarding pathophysiology and treatment of Near Drowning have undergone considerable change. Emphasis in the past focused primarily on electrolyte imbalance which was noted in both animal experiments and in individuals who did not survive the acute drowning episode.^{1,2} The more recent literature regarding near drowning contains reference to fresh and salt water submersion as a type of aspiration pneumonia resulting in a chemical pneumonitis.³⁻⁶

Pathophysiology

Modell and colleagues have demonstrated that the critical problems in cases of submersion are severe hypoxemia, acidosis, and respiratory insufficiency rather than electrolyte imbalance or hemolysis.^{3,6} While acute asphyxia occurs in all drowning victims, near-drowning victims, who by definition survive the acute episode, usually sustain significant hypoxemia.

The common denominator in fresh and salt water near-drowning victims involves hypoxemia and the danger of respiratory insufficiency with concomitant hypercapnea. The aspiration of fluid with associated particulate matter may cause a chemical pneumonitis damaging the alveolar lining cells and may lead to impaired secretion of surfactant. Surfactant, a lipoprotein, lowers surface tension at the alveolar capillary membrane and prevents the tendency for alveoli to collapse as they normally decrease in size during exhalation.

Therefore, in near-drowning cases, surfactant may be diminished and alveoli tend to collapse resulting in atelectasis. The perfusion of these non-aerated atelectatic lung units leads to a physiologic shunt with hypoxemia.

The more fluid aspirated, the greater the loss of surfactant with subsequent atelectasis and hypoxe-

mia. With significant aspiration of large quantities of either fresh or salt water there is a danger of the patient developing large areas of atelectasis, stiff non-compliant lungs, and respiratory insufficiency.

Less critical than respiratory insufficiency are potential fluxes in electrolytes and blood volume which occur in some near-drowning victims. The magnitude of these changes is dependent on the type and volume of aspirated fluid.

There may be a mild elevation of sodium and chloride in some sea water victims, but the levels are usually not life threatening and emergency correction is usually not necessary.

The patients who aspirate large quantities of fresh water sufficient to cause profound electrolyte imbalance and hemolysis succumb to the combined effects of these changes, asphyxia and ventricular fibrillation at the scene of the drowning.

However, in the near drowning victim who survives the acute episode, the key factor in ultimate survival will not be the electrolyte imbalance but ventilatory insufficiency with arterial hypoxemia and acidosis.

Therapeutic Approach

The therapy varies with the severity of the clinical situation. Maintaining a patent airway is of paramount importance in all acute cases. Obviously patients who present as a respiratory arrest require intubation, assisted or controlled ventilation and serial monitoring of blood gases. Patients who develop stiff non-compliant lungs may require controlled ventilation with positive end expiratory pressure.

It should be emphasized that patients who appear stable on observation in an emergency room, following a near drowning episode, should be admitted and monitored with initial and follow-up chest radiographs and arterial blood gases.

A useful guide to approach the alert and stable near-drowning patient who presents in an emergency room would include:

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1. Mandatory admission and observation of all near drowning patients.
2. Serial monitoring of arterial blood gases and electrolytes with correction of hypoxemia and any concomitant metabolic acidosis.
3. Patients who present with the "chemical pneumonitis" of near-drowning should be treated with intravenous steroids. Sputa gram stain and culture should provide hard data in deciding on an appropriate antibiotic.
4. Serial chest radiographs are indicated to document, as well as detect the occurrence of a chemical pneumonitis which may develop hours after the acute episode.

Conclusion

The clinical spectrum of near-drowning patients may vary from a virtually asymptomatic patient with minimal bronchospasm to the patient who presents with the Adult Respiratory Distress Syndrome. Near drowning patients do not demonstrate the severe electrolyte changes that occur in drowning victims who

succumb at the scene of the acute episode. The basic problem in all of these patients who survive the acute drowning episode is ventilation perfusion abnormalities related to atelectasis. Monitoring arterial blood gases and chest radiographs are essential with adequate ventilatory support for those patients with respiratory insufficiency.

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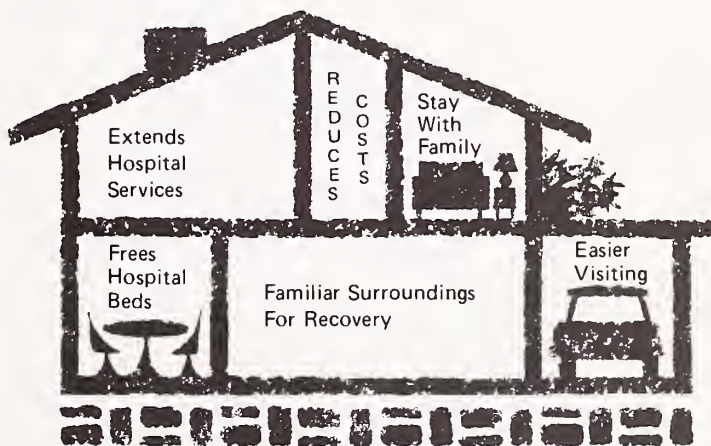
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Caring for the Patient

Bernard V. Strauss, M.D.

In medical school it was necessary for you to learn the details of many different subjects. It was the responsibility of each teacher of each of those courses to provide you with as much information in his field as he possibly could in the time you would be with him. In the process you have acquired a great amount of detailed medical knowledge. What is sometimes missing in the curriculum is a course with the specific purpose of teaching you how to put it all together. From one particular viewpoint, I'd like to make a start on that today. In essence, what I will be talking about is the importance of seeing and caring for the patient as a person with an illness; as opposed to the fragmented and isolated emphasis one may place on a particular disease or organ system.

Let me start by describing two different aspects of caring. In one sense, you, as the physician, "take care" of, minister to, the patient. In another, and this is critically important for good medical practice, you "care for," you are "concerned for" the patient as an individual in difficulty. This is not to imply that you must like your patient. What you do owe him is your concern for the state of his health and well-being. His illness is a confrontation for him. Being hospitalized involves a new and unfamiliar environment, separation from family, fear of the unknown, and a diminished sense of personal identity. The "climate" of the hospital, the general attitude of the nurses, attendants, and other personnel will inevitably affect the patient. Since many of the other hospital people tend to take their cues from the medical staff's attitudes and behavior, there is a great responsibility on the doctor to set a good example. He should seek to convey by action and manner that he cares for his patients as individual people. This is an important aspect of overall patient care. Naturally, each individual will cope with hospitalization in his own way. We should try to be aware of the patient's concerns and to give him opportunity to communicate them to us. We will then be better able to help him.

There is another area in which appropriate communication can make a vital contribution to the patient's welfare. Nurses and social workers have

many opportunities to see aspects of patients behavior that may be kept from the physicians. These observations are, and certainly should be, part of the medical record. But they do no good unless the doctor reads them and discusses them with the nurse or social worker. Too often these notes receive little attention. Communication, written and verbal, between the various professional people involved in the patient's care is essential to optimize that care. It is the doctor's obligation to use all available information which may help him to help his patient.

Years ago when there were relatively few specialists, doctors were able to get to know their patients and families as individuals with particular family constellations, interactions, problems, roles and characteristic coping devices. In recent years, specialists, including those in internal medicine, have tended to concentrate their attention on the scientific at the expense of the humanistic aspect of medical practice. Great advances and scientific achievements have resulted. Somewhere along the way, there has been a tendency to lose sight of the individual with the illness. House calls have become almost a thing of the past. This in itself has sharply reduced the doctor's opportunity to know his patient's home situation, how he lives, how he interrelates with his family. Fortunately, there is currently renewed emphasis on training internists to become true primary physicians. This will involve being the patient's doctor who will treat him for most of his ailments; will refer him to specialists only for needed specific expertise; and will assimilate the reports of the specialists and explain and discuss these with the patient. He will get to know his patient as a person with certain drug idiosyncrasies, with tendencies to react in particular ways; he will probably know his family and how they relate to one another. He will, therefore, be able to help to avoid family frictions which often play a significant part in the patient's illness and how he deals with it.

Some of your patients will be difficult for you to deal with and to care for. In these cases, recognition of transference and counter-transference reactions can be very helpful. Transference refers to the fact that the patient unconsciously carries over or transfers feelings and attitudes engendered in relation to early significant individuals in his life; and now unwittingly directs these attitudes toward current figures whom the patient identifies with the earlier ones. If we can recognize the patient's whining, his anger, his demanding, his irritability; and, conversely,

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This article is a condensation of a paper presented to the residents and medical staff of the Danbury Hospital at the start of the 1976 academic year.

his ready obedience, his reverence, his unequivocal expectations that the doctor will make him "all better," as stemming from past experience and only triggered by the present context, we will be better able to maintain our objectivity, our "cool." We will recognize the patient's unreasonableness as something not entirely within his conscious control. By the same token, it can help for us to recognize in ourselves that the present patient may evoke in us an unreasonable response. He may remind us, and we may identify him with someone with whom we have had an especially meaningful experience—good or bad. We may then treat the patient as if he were "responsible" for that experience. Being aware of the possible source of such reactions on our part, we may question why we are either so taken with this patient or so angry with that one. In either case, we would be better able to see the patient and to treat him as he truly is.

In addition to a complete medical history, a thorough physical examination, and appropriate and indicated ancillary tests and procedures, caring for the patient involves a need to know who this patient is, what were his life circumstances when he developed this illness, what does the illness mean to him, how has his pattern of living been affected, what does he expect will happen to him. These and similar questions are vital to an understanding of the patient and his illness and his particular coping mechanisms. The importance of always taking into account the interaction between the patient's physical and emotional status is most impressively illustrated in a prospective study begun thirty years ago by Caroline Bedell Thomas, M.D., Professor Emeritus of Medicine at John Hopkins University. Let me tell you about one of her more striking findings; one which will serve to underscore the need to take all factors into account in caring for your patient. Of the 113 young medical students with original blood cholesterol levels of over 260 mg./ml. ten had later coronary closures. It was precisely these ten who had scored highest on test scales of depression and tension. It was clearly a combination of the two factors, the high blood cholesterol coupled with a tendency to depression and stress vulnerability that best distinguished the ten who suffered coronary occlusion. Similarly provocative findings of intimate correlations between early physical and psychological status and later illnesses were reported for cancer victims, instances of mental illness and suicide, and hypertension.

It seems to me that the implications for preventive medicine are clear and that the essential emphasis should be on forming the habit of thinking of the whole individual; his personality; his life circumstances; not just his stomach or his heart or

other bodily organ. A combination of factors is involved in the etiology and course of all illnesses. With an awareness of the nature of precursors, we can bend our efforts in the care of our patients toward the various component factors which in combination result in the given illness. What you see in your hospitalized patient is the end product of a multifaceted chain of events and reactions. In order to understand your patient you will need to cultivate the habit of thinking of the interaction of all these elements which impinge upon the individual and to which his illness is his response.

With regard to tests and laboratory procedures—patients tend to respond to these in terms of their emotional status, their expectations, and their interpretations of the reasons for the tests. One patient will appreciate and be reassured by his doctor's thoroughness; another will become apprehensive for fear his physician suspects and is looking for something seriously wrong with him; a third will revel in all the attention he is getting; and a fourth will become fixated on a particular organ system through which he may thenceforth express himself in somatic language. It is clearly important to keep in mind the possible meaning your particular patient may ascribe to your action. To avoid confusion, explain simply; don't elaborate unduly; make clear your therapeutic interest. Remember that an order for a test procedure has ramifications which can at times be anti-therapeutic. Balance your desire to know against your assessment of what is best for the patient.

Remember always that everything you do that is connected with the patient is involved in your caring for the patient. When you write a note in the chart, it should be your purpose to provide a record for yourself and for any other physician who may be now or later involved in the care of the patient. A measure of your interest in the patient will be the effort you make to communicate by writing legibly and understandably.

One's manner of caring for the patient is immediately reflected in the first history-taking session and many patients are sensitive to it. The patient is in trouble. He looks to the doctor for help. It is the doctor's role to generate confidence and understanding. He must avoid becoming sentimental, punitive, or moralistic. It is important to convey to the patient by attitude that one has enough time to hear the patient's story. Let the patient talk. Listen attentively, compassionately, and empathically. Convey that you want to understand, that you want to help. "Listen" with your eyes as well as your ears. Watch movement. What one does is more meaningful than what one says. Don't be afraid to show the

patient that you care for him, are concerned for him—as a person in difficulty—as well as that you will take care of him medically. As I said earlier, this has nothing to do with liking or disliking him. Let him tell you of his life circumstances; don't shut him off. Don't ask mechanical questions. Treat the patient as you would want to be treated. Explain procedures to him in terms he can understand. Don't talk down to him. Don't patronize him. Don't spring things on him. Cover your history outline; but not in a predetermined, sterile order. Let the patient talk. If he is allusive and preoccupied with detail, don't abruptly turn him off. Be respectful of him. Don't be blown up by the patient's need to see you as all-knowing. Some humility will protect you from the inevitable recriminations which follow patient's unreasonable and unfulfillable expectations and demands. Your medical and surgical histories should contain sufficient psychosocial data to enable you to formulate and record a tentative judgment about the nature and extent of their role in the patient's current illness. Don't give empty reassurances regarding either the diagnosis or the treatment outcome. Stay on solid ground with the patient. Don't get involved in long-winded conjectures with him. Tell him what you know to the degree that you can estimate his desire and his capacity to understand.

In cases of medical and surgical emergencies an air of quiet assurance and efficiency will help to lessen the patient's apprehensiveness. In the emergency situation, don't be afraid to be as warm and supporting and reassuring as you can realistically be. If possible, have someone available for emotional support to the family. They will need it.

In addition to the medical and surgical emergencies a variety of psychiatric problems requiring immediate attention may arise in hospitalized patients. It is

urgently important to be alert to these often life-threatening illnesses. Included among them are suicidal depression, post-operative and catatonic excitements, post-partum depression, pathological intoxication, and violent behavior from whatever source.

I will not go into the details of the management of these situations at this time. My present objective is to set down some broad basic principles which underlie a philosophy of comprehensive medical care. Another time we can look more closely at the specifics and identify the indicated therapeutic procedures. We must avoid a cookbook approach. We must keep ever in mind the individuality of the patient.

In cases of suicide attempts, over-doses and others, obviously the first requisite is to treat the acute life-threatening emergency medical condition. Only after you have dealt with that is it appropriate to seek the reasons for the act.

Before closing, I should note that there^o will be instances of patients who will have been admitted because of physical symptoms in whose cases a good psychosocial history will disclose a background which will alert you to the possibility of a masked depression or somatization of some unresolved psychic conflict. However, a word of caution on this score: don't make a psychiatric diagnosis as an exclusion diagnosis. Make it only on the basis of positive findings which will support such a diagnosis, not just because you can't find any physical basis for the patient's symptoms.

Above all, seek to learn to relate the patient's personality, the way he has coped with difficulties in the past, his current life circumstances, school, work, or marital, etc., and the nature and meaning his illness has for him. Only then will you be able to truly care for your patient.

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Informed Consent: Recall by Patients Tested Postoperatively

George Robinson, M.D. and Avraham Merav, M.D.

Abstract—When tested for recall between 4 and 6 months following operation, 20 patients failed to remember accurately major portions of their informed consent interview. Documentation of the details of consent in the clinical record is considered advisable.

It is the patient's right to determine whether he will or will not undergo surgical treatment, and it is the responsibility of the surgeon to provide information for the patient so that he can make an intelligent decision based upon comprehension of the intended procedure. Variations in the standards of adequacy of such information and recent changes in laws across our nation make judgments on the details and validity of informed consent very difficult¹ Several recent legal decisions have transferred evaluation of the adequacy of informed consent from physicians to the jury, and it is now the latter who may decide whether adequate information has been supplied to permit the patient to make a sensible decision with respect to treatment. Certainly, when he is considering whether to undergo a major operation the patient requires information as to the possibility of death or injuries from potential complications. He is also entitled to an expert evaluation of the alternatives to surgical treatment.

The extent to which physicians must inform patients has recently been determined to be that information which is material to the decision-making process. Information regarding complex technological methods, surgical procedures, and prosthetic devices is difficult to transmit to the wide spectrum of patients. Total comprehension by patients, even those with a medical background, may be impossible to achieve, yet the physician is duty bound to inform. By training and experience, the surgeon is accustomed to rendering a prospective analysis of a clinical problem and to evaluating methods alternative to surgery. He should therefore be able to present this material to the patient in a comprehensible form. Documentation of

this transmittal of information in the patient's clinical records has been shown to be desirable.

We have made a conscientious effort to obtain fully informed consent from all our patients undergoing cardiac procedures. Since January, 1975, tape recordings have been made of the informed consent conversations; these recordings were made with the knowledge and permission of the patients. In a carefully structured but informal session one or two days prior to operation, the elements of informed consent were systematically covered in considerable detail.

The outline of information included in each interview was as follows:

1. Diagnosis and nature of the illness
2. Proposed operation, surgical techniques to be employed, and prosthetic devices to be used (if applicable)
3. Risk of death resulting from the operative procedure
4. Potential complications of operation and prosthetic devices (if applicable)
5. Benefits of the proposed operative procedure
6. Alternative methods of management and their chances for failure or success
7. Acknowledgement by the patient of his understanding of all explanations and answering of questions

We were first alerted to the major loss of recall that occurs following the informed consent interview when 2 patients, both of whom were convalescing normally at ten days and six weeks after their operations, denied any recollection of the preoperative recorded interview. A formal study of recall by postoperative testing was then initiated.

Materials and Methods

Between 4 and 6 months following operation, 20 patients were selected for reinterview to determine the capacity of each to recall the details of their informed consent interview. Each of these patients had convalesced uneventfully after a satisfactory postoperative course. Patient selection was otherwise totally random. Ages ranged between 35 and 66 years, with a mean age of 52 years. Nine patients had undergone operation for atherosclerotic heart disease, and 11 patients had been operated upon for acquired valvular heart disease. Recordings were also made at the time of the second interview. All patients had been hospitalized one or more times previously for diag-

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nostic or therapeutic purposes, and none had had their operations performed as emergency procedures.

All informed consent interviews were conducted by one author (G.R.), and all reinterviews were conducted by the second author (A.M.). Before reinterview the original tape recording was replayed, and a chart of the points discussed in each category of informed consent was prepared for rapid reference. At the reinterview each category of the consent procedure was reviewed twice to determine the patient's ability to recall. *Primary recall* was the response to general questions in each category of consent (1 to 6). Questions asked during the primary recall portion of the reinterview were identical for all patients. An effort was made to avoid suggesting responses. The questions were:

- Do you remember having an interview with Dr. Robinson before your operation?
- Tell me what you remember of the interview.
- What were you told about what was wrong with you—the diagnosis?
- What were you told about the operation to be performed?
- Were you told of risks or dangers associated with the operation?
- Were any of the possible complications associated with the operation discussed?
- What were they?
- Were you told in what way the operation would help you?
- Were you told about methods of treatment other than operation?

Following this, the itemized list of topics from the prepared chart was then reviewed with the patient. The patient was asked if each item had been discussed originally and, if affirmative, what the substance of the conversation was. The response of the patient to questions regarding specific items known to have been discussed in the original interview was designated *secondary recall*. Suggestions of correct responses were unavoidable in testing for secondary recall.

Accuracy of primary and secondary recall was then graded 0 to 100% in each of the categories 1 through 6 of the informed consent interview. If there was no recall of a category having been discussed, a score of 0 was given. Partial scores were awarded according to the degree of recall in each category. No deductions were made for denial, fabrication, or errors of attribution.

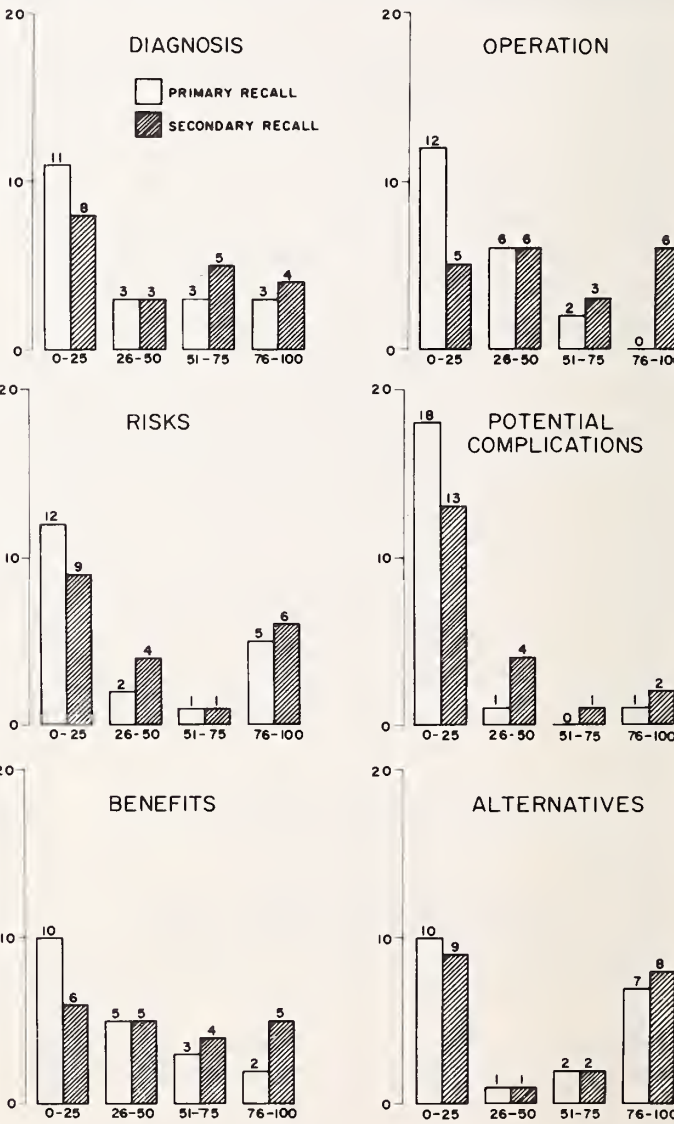
Results

Findings upon reinterview indicated generally poor retention in all categories of informed consent information. The Table indicates the average scores achieved by 20 patients reinterviewed in each of the 6 categories. The poorest scores were achieved in the

RECALL OF INFORMED CONSENT INTERVIEW BY 20 PATIENTS
4 TO 6 MONTHS POSTOPERATIVELY

Category of Informed Consent Information	%	
	Primary Recall	Secondary Recall
1. Diagnosis and nature of illness	33	46
2. Proposed operation	26	51
3. Risks of the operative procedure	35	42
4. Potential complications	10	23
5. Benefits of the proposed operation	29	47
6. Alternative methods of management	43	43
Average	29	42

single category of potential complications: there was 10% primary recall and, with the suggestion of appropriate responses, a secondary recall of 23% out of a possible 100% for this category. The average recall in all categories was 29% for primary and 42% for secondary recall. Thus, even with the influence of suggestion and a point-by-point review of every item covered in the original interview, patients could remember only 42% of the items that had been covered in the informed consent interview. The Figure illustrates the scores achieved by percentage groups in



each category and demonstrates the improvement in secondary recall. Of the 20 patients tested, 17 scored 50% or less on primary recall and 12 scored 50% or less on secondary recall. The lowest individual score achieved was 3% primary and 3% secondary recall, and the highest score achieved was 57% primary and 87% secondary recall.

Errors made by patients in the repeat interview had qualitative differences. They may be described as failure to recall; positive denial of a truth; fabrication, or the assertion of an untruth or falsehood; and errors of attribution.

Each of the 20 patients failed to recall major parts of the interview. Sixteen of the 20 patients positively denied that certain major items had been discussed at all. Of these 16 patients who made positive denials, 13 denied having been informed on multiple (maximum of eight) significant items of information. After failure to recall and denial, the next most common error was fabrication, or the assertion of an untruth or falsehood. This was present to a significant degree in 13 of the 20 patients reinterviewed. A common error (and one that is quite understandable) was attribution of information gathered from other sources to the informed consent interview.

Two patients voluntarily complained that the preoperative interviews were very brief, inferring that they were not informative. One of these stated that "all he did was lift up my shirt, put a stethoscope on my heart, and that was it." The recorded portion alone of this informed consent conference was 24 minutes long. The second complaint about brevity of the interview came from a patient whose recording lasted 23 minutes. The unrecorded portions of each consultation visit easily exceeded 10 additional minutes.

Noteworthy was a significant difference in the self-assurance with which patients responded to questions in reinterviews. The quality of responses to questions often indicated some doubt or lack of certainty. Three patients were considered to have a quality of response that indicated near total self-assurance in being correct in the details of recall. The poorest score of all 20

patients reinterviewed was achieved by a patient who responded authoritatively and expressed no doubts regarding his recollections. Two other patients, who scored fifteenth and seventeenth, respectively, also had the same quality of response: they were frequently in error but never in doubt.

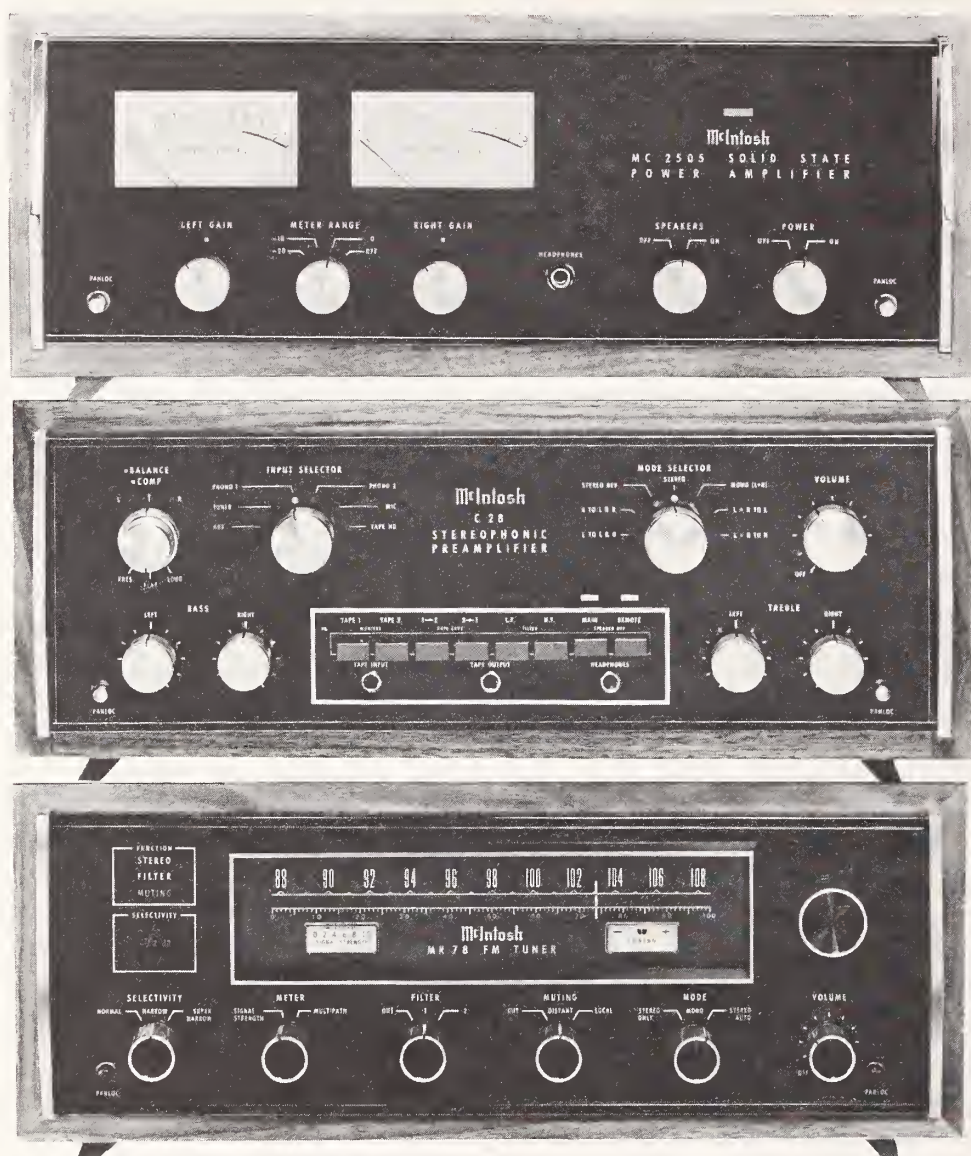
Comment

Despite meticulous attention to detail by the surgeon in a carefully conducted informed consent procedure, all of 20 patients tested between 4 and 6 months postoperatively failed to recall accurately what had transpired at their interview. The informed consent had been given in a simple, direct, and uncomplicated manner in the form of a dialog between the patient and the surgeon. There were repeated instances in each conversation in which the patient was asked if he understood the explanations, and questions were answered as they arose. We believe, therefore, that all patients completely understood the information imparted and that they gave a truly informed consent to their operations. Noteworthy is the fact that the patients studied had been educated by their previous experience with their disease; all had chronic heart disease and had been hospitalized many times for diagnostic and therapeutic procedures. This study calls attention to the fact that, while these patients were well informed and comprehended their situations prior to operation, they subsequently forgot most of what they had understood and made other qualitative errors in their attempts to recall the consent interview. We believe it is essential to document in some way the details of informed consent so that it becomes a permanent part of the clinical record, since memory of the event is unreliable.

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The Nature and Extent of Research Involving the Human Fetus

A 1975 Literature Review

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Abstracted by Florence Keller, M.D.

An extensive literature review of human fetal research was undertaken in 1975 for The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The review had been mandated by the United States Congress. Following is an abstract of the review prepared by Dr. Florence Keller. The full report with bibliography is available from the Department of Health, Education, and Welfare.

To prepare the report, the literature review was organized in the four general categories which follow.

1. Fetal Growth and Development in Utero

Over 600 publications were reviewed, half of which dealt with anatomic parameters and half with physiologic and metabolic information. The anatomic studies were carried out with human fetuses from both spontaneous and induced abortions. All modern modalities from electron microscopic examination thru nuclear resonance techniques have been used. The physiologic and metabolic studies required living fetuses or live fetal tissues as well as preserved fetal material. Techniques included amniocentesis, angiography, fetal lymphocyte isolation from maternal blood, sonography, amniography, and fetoscopy as well as tissue cultures and biochemical assays. Some of these studies, such as umbilical cord blood and scalp blood studies, are nonbeneficial for the fetus participating, but they carry low risk and are essential to establish normal data in order to diagnose and evaluate abnormal conditions.

Fetal behaviors have been studied via observations in utero using sonography, electroencephalography, radio opaque dyes and radiolabeled blood cells. With these methods breathing and swallowing have been

documented and studied. Effects of sound and light have been evaluated by monitoring fetal heart rate responses to the stimuli. Observations of previable fetuses outside the uterus were used to evaluate reactions to touch as early as 7 weeks gestation.

Physiologic and pharmacologic studies with pregnant women have been largely done without reporting the effects, if any, on their fetuses. Factors examined here included dietary changes and effects of drugs such as insulin, glucose, and angiotensin II on maternal physiology. In general the studies in women were patterned after prior studies in lower animals.

2. Diagnosis of Fetal Disease or Abnormality

Detection of genetic defects, excluding blood group incompatibility, have been the subject of over 800 papers since 1966. The approaches used included amniocentesis for the study of amniotic fluid and amniotic fluid cells; radiologic techniques including fluoroscopy, amniography, fetography, and sonography; examination of fetal cells from the maternal circulation; measurement of fetal metabolites in maternal urine; and fetoscopy with fetal skin biopsy and blood sampling.

Of those disorders in which specific inborn metabolic errors have been identified, over 60 can be detected by amniotic fluid cell studies in vitro and more than 25 have been successfully diagnosed in at risk pregnancies.

Some structural defects can be identified by fluoroscopy, amniography, or fetography in early gestation. Intrauterine fetal transfusion has been accomplished and treatment with hormones and drugs has been suggested by these experiments. Ultrasound techniques have also provided important information concerning growth and development in utero.

Rh incompatibility between mother and fetus has been widely studied and transfusion therapy developed for the fetus. Understanding of the hematologic

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interrelationships have in turn made possible the prevention of Rh isoimmunization in most women today.

Diagnosis of inborn metabolic errors has been largely used for genetic counseling. For the most part treatment is not yet available but elective abortion may be offered. This has presented a number of genetic and ethical concerns which have been widely discussed.

Neural tube defects have been sought with roentgenography, sonography, and direct fetoscopy. In addition several biochemical determinations have been developed. The visualization techniques are only applicable in the second half of pregnancy whereas elevated alpha-fetoprotein concentrations in amniotic fluid and maternal serum are detectable at 10-20 weeks of pregnancy.

Measurement of lecithin relative to sphingomyelin concentrations in amniotic fluid (L-S ratio) has been useful in determining lung maturity in at risk pregnancies. Research has also been carried out in an attempt to develop methods to speed up lung maturation by administering various drugs. The possible hazards of this approach, whereby a multiplicity of effects might occur when only a single organ is the target, are likewise being investigated.

More than 100 papers between 1969 and 1974 have been devoted to assessing the safety of amniocentesis. Most reports deal with third trimester procedures. One extensive study of second trimester amniocentesis was completed in 1975. All studies concerning the safety of amniocentesis have been encouraging. Because of important species differences, nonhuman studies have had limited use.

Diagnostic ultrasound applications and hazards have been investigated at all stages of pregnancy and to date ultrasound appears to be quite safe from several studies where children were followed to 7 and 8 years of age.

Pelvimetry and various radiologic techniques for the diagnosis of multiple pregnancies and bony abnormalities have been reported many times. Amniography and fetography have also been used. Such techniques have been applied in full recognition of the biological hazards of x-rays. Extensive plant as well as animal experiments have been carried out in an effort to clarify and assess the hazards.

Separating fetal cells out of the maternal circulation is a new field of investigation. This may eventually prove of great use in genetic analysis of the fetus. It has been found that fetal cells may persist in the maternal circulation for over two years. Certain by-products of fetal metabolism are found in maternal urine and these are now widely used to check fetal wellbeing.

Fetoscopy is another new investigative tool. It enables researchers to view the fetus for physical abnormalities and presents the opportunity to obtain fetal blood samples and skin biopsies. Current work has dealt largely with fetal diagnosis but ultimately preventative and curative treatment will follow.

3. Fetal Pharmacology

In the area of developmental pharmacology it is often difficult to separate studies directed toward understanding the pharmacology of the fetus and those directed toward treatment of the pregnant woman.

Most of the studies directed primarily toward the fetus were carried out close to delivery or during the paraptum period. Invasive or potentially harmful procedures have included amniotic fluid sampling, scalp vein sampling at the time of parturition, fetal blood sampling during fetoscopy, prepartum fetal blood transfusions containing drugs, and drugs administered to the mother for therapeutic reasons or placental passage studies. Noninvasive and minimal risk procedures include fetal electrocardiography and umbilical cord blood analysis with the fetus in situ. Isolated tissue studies to study drug metabolism were carried out in vitro on biopsy material obtained after fetal death.

Little is known concerning the effects of drugs on the human fetus. Studies concerning agents used in early pregnancy have always been retrospective; they have involved oral contraceptives, drugs of abuse, and several over-the-counter medications. Drugs used in a medically accepted manner for the treatment of illness in the mother have usually been investigated only after some question has arisen as to untoward effects on the fetus. These drugs include anti-infectives, hormones, antineoplastic drugs, immunosuppressives, anticonvulsants, drugs of abuse, and local anesthetics. Societal pressures to produce safe, relatively painless birth have given impetus for investigations of drugs used during parturition.

Data on drugs which cross the placenta have been studied indirectly by drug administration to the mother prior to abortion and analysis of tissues obtained from the fetus shortly after death. Application of these data to the treatment of fetal disease has been evaluated. Some placental drug transfer studies have involved molecular configuration and physical chemical properties of a drug as they relate to placental transfer in order to permit treatment of the mother without fetal involvement, that is, without the drug crossing to the fetus.

Determination of the most effective mode of administration of drugs to the fetus and the nature of fetal distribution of the drugs is also being studied. Studies in subhuman species have been widely carried

out but are not particularly applicable to the human fetus. Placental function differs widely among species as does tissue distribution and biochemical differentiation. At present, in vivo information in the human is minimal.

Drug effects on specific physiologic processes unique to the maternal-placental-fetal unit are being investigated. For example, vasoactive drugs have been extensively studied in the umbilical and placental circulations in order to determine their effects on fetal circulation, fetal cardiac output, and survival. The fetus and placenta act in a synergistic manner with respect to maternal treatment with various hormones. The interrelationships have been and are being extensively studied.

4. Research with the Previaible Fetus Outside the Uterus

In this area definitions are of the essence. Distinctions must be drawn between organism death, organ death, tissue death and cellular death. Most reported research in this field has been done with fetuses which are clearly dead as organisms. Tissues are used for cell culture, transplantation into defective living persons, and for the growth of human viruses.

Research on fetuses outside the uterus can be classified according to degree of intervention with the fetus. Thus, observation is minimal intervention and collection of body fluids and tissues is more invasive. Most research on previable fetuses is done according to protocols which are also applied to viable fetuses or premature infants. In this regard there is no clear distinction between fetal research and neonatal research. The work is meant to be either beneficial to the research subject or is done in a manner that would not limit the subject's ability to achieve viability.

Only small numbers of studies with living previable fetuses outside the uterus have been done. They have included studies which demonstrate the ability of the fetal brain to metabolise ketone bodies and studies of the endocrine functions of the placenta and fetus separately. Amino acid levels in malnourished fetuses and total body water in low birth weight newborns have been measured.

Attempts to prolong the life of previable fetuses by various artificial environments have been carried out. The development of a fetal incubator for humans was tried after model studies had been done with mice. Perfusion of oxygenated blood thru the umbilical ves-

sels was tried on spontaneously aborted fetuses as well as similar experiments on hysterotomy fetuses. Brief survival was achieved.

Summary of Literature Review

Several thousand reports on research in fetal medicine have been published during the past ten years. A large percentage of reports dealt with research on the fetus in utero and were directed toward management of fetal problems. Alterations in obstetric practice, including monitoring of the fetus, resulted in decreased perinatal mortality. Diagnostic capabilities have been enhanced with increasing attention to the fetus in early gestation. Evaluation of maturity, abnormalities, and disease has progressed to a beginning development of therapeutic possibilities for the fetus.

Minimal risk techniques have furnished information on normal pregnancies in parallel to the abnormal. Much information on the mid-trimester fetus has been developed in the setting of induced abortion. Investigation of normal human development has been largely observational and much effort has been focused on physiologic, biochemical and pharmacologic data. Most work on living fetuses has not put the fetus at any increased risk. Much valuable data has been obtained from tissues of aborted fetuses.

Usually human experimentation has followed animal experimentation. Large species differences have emphasized the need for primate research.

Fetal tissues are being used increasingly in the areas of virology, cancer research, and transplant therapy. In this area the definition of death has been an important issue. Little work has been done on extrauterine previable fetuses and studies with artificial incubators have been discouraging.

Techniques of sonography, electrocardiography and electroencephalography, which are non-invasive, are furnishing interesting information in the fields of fetal behavior, psychologic development, and sensory perception. Ethical issues have been rarely mentioned in published reports of fetal research, but recently the question of legal sanctions have been introduced with respect to abortion and the use of aborted fetuses.

Continued fetal research is necessary to overcome the many problems of fetal life and to gain further insight into human biology. Intelligent regulation of the research is also required to guarantee needed protection to the fetus while permitting the research to proceed.

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National Health Insurance

With the approach of a new Congress and a new Administration the Board of Trustees has undertaken an extensive review of national health insurance. The reason: it is important that the position of the Association be made clear at an early date. The Association must continue to exert its leadership so that medical care is rendered in a system which provides for improvements, scientific advancement, and the highest quality in patient care. As a result of this review, the Board submits to the House this summary of its analyses, conclusions, and recommendations.

Mindful of the deep concern of members of the House of Delegates relative to national health insurance, the Board initiated special procedures in order to provide a comprehensive review of the subject to determine whether AMA policy continues to meet the needs of the public and the medical profession.

Shortly after the 1976 Annual meeting the Board created an Ad Hoc Committee composed of members of the Board, the Chairman of the Council on Legislation, and the Chairman of the Council on Medical Service solely to consider the subject of national health insurance. In addition, the Board referred national health insurance to the Council on Legislation and the Council on Medical Service for their own comprehensive review. These Councils have evaluated the many complex factors bearing on the subject and have presented to the Board their views and recommendations.

These Councils, the Special Ad Hoc Committee of the Board, and the Board itself are unanimous in their recommendation that 1) the Association should support its own national health insurance program in the 95th Congress, and 2) HR 6222 (with perfecting modifications identified by the Council on Legislation) be reintroduced.

Support for National Health Insurance

House of Delegates actions on NHI have spanned eight years. At the Clinical Meeting in 1968 the House adopted the principle of graduated income tax credits on insurance premiums and called for the AMA to draft and promote federal legislation to implement the principle. In June 1969 the House received a report from the Board of Trustees announcing completion of consideration of a proposal for federal income tax credits. The report stated that the proposal had been forwarded to the Council on Legislative Activities for drafting of appropriate legislative language. At the 1970 Annual Convention the House approved Report V of the Board of Trustees which formally

presented the "concept and design" of AMA's Medcredit bill. A draft of the Health Insurance Assistance Act of 1970 was approved. This was the first official recognition of the term "Medcredit" by the House of Delegates.

Medcredit principles and concepts were defined by the House at its meeting in June 1971. The House called for an NHI program that 1) provides insurance protection with comprehensive benefits and also catastrophic protection; 2) promotes freedom of choice; 3) provides that any federal funding should be through general revenues and be related to an individual's income; 4) requires reasonable cost sharing features; and 5) provides for state government approval of participating insurance plans.

Thus, AMA support of a National Health Insurance plan antedated introduction in 1970 (in the 91st Congress) of its first Medcredit bill, officially known as the Health Insurance Act of 1970 (HR 18567). Subsequently, NHI bills supported by the AMA were introduced in the 92nd, the 93rd and the 94th Congress. These bills were founded on policies established by the House of Delegates.

The first bill in 1970 and all later proposals utilized the present private-sector health care and health insurance system. All bills concentrated the use of tax funds toward helping persons in financial need. All bills stressed the importance of equal access and quality of care. All bills featured comprehensive coverage.

The original comprehensive Medcredit plan proposed a tax credit system to off-set the cost of private health insurance. Subsequent bills were modified to incorporate improvements in both benefits and administration. The plan was expanded in 1971 to include catastrophic coverage. Dental coverage for children and home health services were added in 1973.

HR 6222, the Comprehensive Health Insurance Act of 1975 (the latest of AMA's bills), embodied a concept not included in the previous proposals. Special tax consideration was included for both individuals and employers; employers were required to provide comprehensive health insurance coverage for their employees on a shared-cost basis. For employees, however, the insurance was optional.

The Comprehensive Health Care Insurance Act of 1975 (HR 6222) was endorsed by actions of the House of Delegates in June 1975 and June 1976. Since 1970, AMA leaders have testified many times before Committees of Congress in support of AMA national health insurance policy. The AMA National Speakers Bureau has provided spokesmen who have in various forums presented the AMA view on the NHI issue.

AMA Principles

Basic AMA principles have not been relaxed throughout the Association's legislative involvement in NHI. For example: Any national plan should build on existing private insurance and should not be operated as a government service; the plan should be financed by private payments for insurance coverage for those with ability to pay and from general tax funds for low income groups; the plan should utilize the pluralistic health care systems; the benefits should be comprehensive, embracing both basic and catastrophic coverage; there should be minimum federal involvement; no payroll tax and no administration under Social Security (which are the elements of a National Health Service System); the program should include appropriate cost sharing; federal subsidies should provide assistance for those in need. HR 6222 clearly embodies the principles repeatedly endorsed by this House.

Comprehensive vs Catastrophic

One of the most important questions which faced the Councils and the Board in their review was: What should the AMA bill be? Should it provide for comprehensive coverage or should it be free-standing catastrophic? The Board and the Councils have again concluded that the AMA bill should provide comprehensive coverage, i.e., both basic and catastrophic.

The AMA bill provides comprehensive benefits through the private health insurance system, is financed through employer-employee contributions, includes federal funding for the low income and the unemployed, has limited federal involvement, and builds on the strengths of the present health care system.

Comprehensive coverage, including both basic and catastrophic, provides the full range of benefits necessary for the individual's health care needs. This protection assures the individual of necessary coverage at an initial stage and thus would cover the greatest likelihood of need for most persons. Moreover, comprehensive coverage recognizes there should be protection against those unpredictable instances in which catastrophic illnesses do occur.

On the other hand, free-standing catastrophic simply does not meet the needs that a NHI program seeks to address. It lends itself to the kind of manipulation which could easily change the character of the program from limited federal involvement to minimal private involvement.

The House in June 1972 stated that a federal program of catastrophic coverage should not be free-standing but should be related to provisions for comprehensive basic benefits. This view was reiterated as recently as the last meeting of this House, when the House adopted the Report of the Council on

Medical Service which stated: "The Council does not believe . . . the Association can properly seek or assist in the formulation of free-standing catastrophic coverage plans."

No Position or Non-Support

The Board of Trustees considered the argument that the Association should not support any national health insurance program or participate in development of any NHI program.

At a special conference held immediately after the recent Presidential elections, the Trustees received the views of top leadership of a number of health organizations. In attendance at the meeting were representatives of the American Hospital Association, the American Dental Association, National Association of Blue Shield Plans, Blue Cross Association, Health Insurance Association of America, the Farm Bureau, Washington Business Group on Health, the Chamber of Commerce, the Federation of American Hospitals, the American Medical Association, the AMA Inter-specialty Advisory Board, and Members of Congress together with staff from key health committees.

The message came through loud and clear that it was necessary and desirable for the AMA and others who had sponsored NHI bills in the Congress to continue their advocacy through such means. The consensus was clear that abandonment by the AMA of support of an NHI bill in the Congress would be extremely damaging to the maintenance of a role for the private sector.

Moreover, Members of Congress have specifically counseled against any Action of the Association withdrawing support for a national health insurance program, stating that to withdraw from the issue of national health insurance would amount to abandonment of its responsibilities to the Congress and to the public.

Representative of various views received by the Board are the following observations made by the Council on Legislation:

"To take a position, in effect, of 'no position' on national health insurance would be interpreted by most people as abdication of the present and past position of the AMA in support of a proper national health insurance program. Similarly, a position of not supporting any bill for national health insurance would be undesirable as amounting to a decision not to participate in the development of any national health insurance program which may receive consideration in the Congress.

". . . It is important and necessary that the Association should take a position of involvement in the development of any national health insurance program and that the AMA should support a national health insurance program reflecting its views.

“...The Association’s active influence could be effective in shaping a proper national health insurance program in the interests of the public, could play a major role in meeting the concerns of the medical profession, and could provide the best means of assuring financial access to health care for patients, while maintaining appropriate approaches to administration and financing through the private sector.”

The Board concurs unanimously with these conclusions of the Council.

Continued Support for HR 6222

Another issue addressed by the Board centered on its continued support of HR 6222. The Board reviewed the benefits resulting from introduction of HR 6222 in the last Congress and noted that HR 6222 provided an effective forum for AMA participation in NHI discussions. HR 6222 has provided a vehicle through which the Association could actively participate in a realistic formulation of NHI policies in Con-

gress. To change that support could result in diminishing AMA’s voice in any further development of NHI. HR 6222 provides a realistic approach to the question of NHI. It embraces AMA-developed principles and meets the Association’s concern for the health care of the American people.

Conclusion

After a full consideration of the many issues involved, the Board is of the opinion and recommends that the Association should reintroduce a national health insurance program in the Congress. Furthermore, the Board is equally convinced and recommends that HR 6222 (carrying appropriate amendments identified by the Council on Legislation and approved by the Board of Trustees) is the appropriate program to be endorsed for the 95th Congress. HR 6222, founded upon the fundamental principles adopted by the House of Delegates for national health insurance, can effectively accomplish the Association’s goals.

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DATE TIME
BUN 10.26 mg/dl
Creatinine 0.7-1.4 mg/dl
Total Protein 6.0-8.5 gm/dl
Albumin 3.0-5.5 gm/dl
Cholesterol >40 150-330 mg/dl
Triglycerides 30-175 mg/dl
Uric Acid 2.5-8.0 mg/dl
Calcium 9.0-11.0 mg/dl
Phosphorus 2.5-4.5 mg/dl
Serum Iron 37-184 mcg/dl
Globulin 2.4 gm/dl
BUN/Creatinine 10:1 Ratio

SEQUENCE NO. 827
Total Bil 0.2-1.2 mg/dl
SGOT 0-48 U/L
SGPT 0-45 U/L
Alk Phos 30-115 U/L
LDH 100-235 U/L
Sodium 135-145 meq/L
Potassium 3.5-5.0 meq/L
Chloride 96-106 meq/L
Carbon Dioxide 19-26 meq/L

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Ethical Safeguards in Research

Stephen Toulmin

The legislation that established, in 1974, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research grew in part out of the general disaffection with science during the late nineteen-sixties and early nineteen-seventies. More particularly it was a response to newspaper stories about fetal experimentation and experiments with syphilitic inmates in the Alabama State Prison at Tuskegee. The specific occasion for the legislation was the strong move in Congress (following the Supreme Court's ruling in 1973 legalizing abortions) to ban all federal funding of fetal research. Senator Edward Kennedy persuaded the Senate to accept a recommendation by his Health Subcommittee of the Labor and Welfare Committee for a four-month moratorium on funding, during which time the new Commission developed guidelines to regulate fetal experimentation. This was intended to defuse the issue and move the substantive decisions outside the then overcharged atmosphere of the Congress.

The Commission, set up for an initial two-year period (January 1, 1975, to December 31, 1976) has eleven members. Five are medical or behavioral scientists, the rest are lay people—three from law, two from moral theology, and one public-interest representative. Three of the commissioners are women, two of them blacks. The members were nominated by the Secretary of the Department of Health, Education and Welfare after consultation with the senators most directly involved. All but two have academic positions. The commissioners elected as their chairman Professor Kenneth Ryan, the head of the Department of Gynecology at Harvard University Medical School and director of the Boston Women's Hospital.

The Commission is instructed to report on three general sets of topics and to make recommendations for action, both to the Congress and to the Department of Health, Education and Welfare. First, the Commission must propose guidelines for the federal regulation of research on certain special populations of research subjects: human fetuses,

prisoners, institutionalized psychiatric patients, children, and other "captive groups."

Second, the Commission must survey existing arrangements for the ethical review of research projects involving human subjects in universities, hospitals, and other places where federally funded biomedical and behavioral research is done, and propose whatever revisions and modifications it deems necessary.

Third, the Commission must prepare a general report on the legal, social, ethical, and public policy implications of novel biomedical and behavioral technologies.

On the third set of topics, the Commission will report directly to the Congress. In the other two areas, it has further unusual powers. It is instructed to make recommendations to the Secretary of H.E.W., who is required to publish them in the *Federal Register* and then to issue formal guidelines regulating the corresponding types of research. In any case where H.E.W.'s guidelines depart from the Commission's recommendations, the Secretary of H.E.W. is required by Congress to explain publicly the reasons for not following the recommendations.

The powers granted by Congress to the Commission amount to something like deputed legislative authority in the regulation of human experimentation. Thus, a group of eleven citizens is empowered to frame both principles and detailed recommendations. This is a novel way of drawing non-elected experts into the legislative process. Also novel is the fact that for the first time the legislative and executive branches of government have established formal institutional procedures for the regulation of scientific research.

Public regulation of science is a thorny and complex issue. The problem of balancing the First Amendment right of freedom of inquiry against the public interest, and the other rights of those who can claim to be affected by research, deserves careful discussion. The status of scientists is directly affected by this development. Until now, scientists have escaped any demands for formal licensure such as apply to physicians and attorneys. Already, as a result of the Commission's public hearing, some civil-liberties groups have demanded licensure—at the least—for medical research workers, who need not be doctors of medicine as long as their research is either non-invasive or supervised by an attendant physician. The long-term implications of any demand for

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scientific research workers to be licensed need to be examined with some care.

When the modern scientific movement began in the seventeenth century, the people who were interested in developing what we now call the natural sciences operated under two symbolic tutelary figures, Francis Bacon and Isaac Newton. Bacon advocated state support of natural scientific activities for utilitarian reasons. He argued that, by supporting scientists, the benefits of their activities would redound to the citizenry at large. Once the scientific enterprise really got going, however, Isaac Newton became the dominant figure, and scientists worked for two hundred years in ways that bore little relationship to questions of a utilitarian kind.

Scientists saw their enterprise as one over which they were entitled to complete control, and they developed their own institutions to promote and regulate their activities. They sought to present science as being politically neutral, and they tried to insulate it from involvement with the state. The underlying presumption was that scientific research was intrinsically valuable and, at the very least, harmless. To the extent that society accepted this presumption, there was no reason to object to scientists doing their work. As a result one can view eighteenth- and nineteenth-century science as having been a magnificent intellectual activity, worthy of high praise, but not yet ready to make direct social contributions; or one can view it more cynically as Jacques Barzun has done, and say that, while science claimed to be for the good of society, in fact it was a "glorious entertainment." Either way, the scientists entered the twentieth century with a network of institutions and a pattern of activities carried on without any kind of directive or controlling reference to social good or harm.

Since the first explosion of nuclear weapons in 1945, the burden of demonstrating whether scientific research is harmful or harmless has been moving away from the critics onto the scientific community. Since 1965, this burden of proof seems to have shifted decisively and irrevocably. From now on, scientists will have to prove the "harmlessness" of their projects in every case. Still, our society has no accepted mechanisms for the public review of the legitimacy of scientific research.

Against the idea that society needs such mechanisms, including licensure, scientists plead the First Amendment. They claim there should be no prior restraints on or state intervention in this indispensable human activity.

With few exceptions, there are no public sanctions which can be invoked against scientists for "improper" conduct of research. Scientific research is open

to public challenge, first, if it involves human beings as experimental subjects; or, second, if it involves the use of dangerous substances or large-scale effects on the environment. Scientists are subject to control by the Food and Drug Administration, and to the normal restraints of the Environmental Protection Agency and its various state counterparts.

It is also possible for specific research projects to come under public review at the request of the scientists involved in them. The best-known example of this is the "recombinant" DNA research in which a group of molecular biochemists asked the National Institute of Health for guidance in the conduct of their research.

So there are these three areas in which public mechanisms have been developed to appraise scientific research: where it involves manifest dangers or damage; where the scientists themselves ask for an appraisal; where the research involves the use of human beings as research subjects. It is to deal with the last that the Commission was created.

Although the Commission works in several areas, its most directly influential activity is the drafting of guidelines to regulate research involving people who need special protection. When the Commission was set up, great anxiety was being expressed in the press and in Congress about the use of human fetuses for biomedical experimentation. Other topics which became annexed to the Commission's agenda concerned the use of prisoners in the first phase of drug testing; retarded children in institutions; the institutionalized mentally ill; children below the age at which they could understand what was being asked of them; the comatose; the terminally ill; and other classes of people who, it was felt, were not in a position to give free and informed consent to experimentation.

The participation of human subjects in biomedical and behavioral experimentation can be called in question in two kinds of situations: in cases where the individuals do not seem to have an adequate opportunity to give their consent freely, however well-informed they may be (prisoners, draftees, and others within what sociologists call total institutions); and in cases where they are at risk because they lack the capacity to understand what is being required of them. (e.g., infants, acute schizophrenics).

The Commission has found that the issues depend upon the particular combination of deficient opportunity and deficient capacity that exists. As one moves from retarded children to institutionalized schizophrenics to fetuses to prisoners, the issues balance off against one another interestingly different ways.

Most impressive has been the way in which the Commission members have formed a common mind. There are certain divisions within the Commission; its members come to the various issues with different emphases. All the same, they have managed to work out ways of discussing and pursuing the factual bases of the issues.

When one hears the word "commission," one often thinks of Presidential commissions (on obscenity, marijuana, or violence) which produce documents that are filed away and never heard of again. The powers Congress has given to the Commission make it impossible for its recommendations to be ignored, because of the requirement that the Secretary of H.E.W. must publish them, promulgate his own regulations, and give a public explanation of any variance between the two.

No additional legislation is required to put the recommendations of the Commission into effect. It is within the authority of the Secretary of H.E.W. to make known the conditions under which H.E.W. will authorize the funding of scientific research.

The Commission is not an enforcement agency. Enforcement is carried out by H.E.W. on the basis of the Commission's recommendations. This is one of the first conscious and deliberate attempts to deal with the problems that arise the moment that scientific research begins to take forms which raise questions of ethics and public policy.

Research guidelines do force young scientists to face the ethical issues involved in their work. When a scientist is in a situation in which he is tempted to do research which he thinks may fall foul of the human subjects review committee, he can respond in one of two ways. He can say that it's too much trouble and abandon the research. Or he can ask himself whether he can get the same knowledge by changing his original research design so that it is not open to objection. In the long run, the latter will probably be the more frequent response. The practice of making one's research design not only rationally effective, but ethically acceptable, seems destined to be a part of the training of every prospective scientific research worker.

The law relating to freedom of inquiry is not as clear as the law relating to freedom of speech and publication. Where this matter has come before the courts, there has been a strong inclination to treat freedom of inquiry as a special case of freedom of speech. And if the case against prior restraint to prevent government interference in scientific experimentation is going to be fought in the courts, the case will probably be laid on a First Amendment basis.

When the Commission was set up, it used as the first pattern a set of considerations about biomedical

research that is physiologically intrusive. But I am concerned about the fact that these biomedical-research procedures and guidelines were extended to the whole area of behavioral research in a way that was simply not thought out.

Let me give an example. The institutional review board at one university told its social scientists that under no circumstances must they engage in research involving the interviewing of people over the telephone, because one cannot get a signed consent over the telephone. It should surely be sufficient to tell those who do telephone interviewing to follow something like the Miranda rule: that they must identify themselves and tell the persons they are questioning that they are at liberty to hang up at any time, that they do not have to answer, etc.

The trouble with extending biomedical procedures to the behavioral sciences is that the ethical issues involve different branches of the law. When the notion of free and informed consent was first formulated, the issue was intrusive surgical or physiological procedures that could lead to physical injury; and that involves battery or negligence. In the case of social research, however, it is not battery as much as privacy that is relevant. In the latter case, it is important that information obtained from subjects of research should not leak out to the public. H.E.W. wants to be sure that social science researchers protect the confidentiality of their subjects. But it is just not the case that the ways in which human subjects can be protected against unjustifiable surgical intrusion in biomedical research are sufficiently analogous to the ways in which social scientists must protect their subjects against a breach of confidentiality or a violation of their privacy.

An informed-consent document serves a quite different function in the context of a surgical or physiological procedure than it does in other cases. Suppose, for instance, that research is being done on drug users or homosexuals. It may be more dangerous to the human subject to sign a consent form, and thereby put on record the fact that he is a drug user or a homosexual, than to participate in the inquiry itself. One can make the case that the right thing to do is to make sure that the subject is a willing and knowing participant in the research, and that compelling him to sign a form attesting that he is a willing and knowing participant cannot be made a necessary condition in each instance.

When the Commission began working on the problem of research involving prisoners, many of us were receptive to the widely held conviction that conditions in prisons were intrinsically coercive and thus free consent on the part of the prisoners to participate in research was probably impossible. This was the basis of the case which the American Civil

Liberties Union put in public hearings to the Commission.

We went to Southern Michigan State Prison at Jackson and talked with prisoners under conditions which I think were reasonably satisfactory. We talked with those who had participated in research and with those who had not. Many of the prisoners were indignant at the idea that their opportunity to participate in research might be taken away from them. Although it had been argued to us beforehand that the prisoner volunteers were "victims" exploited by predatory research workers, we discovered that the first to volunteer in this research are often the best-educated and most intelligent prisoners. All information about their participation or non-participation is kept out of the records which come before the parole board.

Research participation yields three immediate rewards for the prisoners, of which we foresaw two. One is that they can go into a decent environment where a lot of agreeable things happen. It takes them, at least to some extent, out of the sense of being incarcerated.

Second, they get something approximating real money. The scale of rewards for normal prison labor ranges from fifty cents a day to a maximum of eighty dollars a month. By participating in research, prisoners can get up to two hundred dollars for each project. Prison authorities (many of us felt) operate an exaggerated version of the free-enterprise, capitalist economy within the prison, manipulating and controlling the prisoners. Being able to get money, real money, is of great importance to prisoners. The degree of comfort which they can obtain varies according to their ability to get hold of money.

The third benefit was a surprise to the commissioners. A fair proportion of the prisoners who participated in research told us that they volunteered for it because the research facilities are the only place in the prison where they can get a good physical examination, which is prerequisite to participation. One man said he had been given no examination by the prison doctors since the one he had received when he entered the prison nine years previously.

After the prison visit, it was noticeable that when the commissioners discussed the issue of prisoner research, they started formulating their recommendations not on the basis of whether the institution is so coercive that consent is invalid, but rather as a balance between the prisoner's right to volunteer the coerciveness of the institution.

In the case of fetuses and very young children, there is no doubt that, looking at this from even a legal standpoint, the notion of proxy consent is very confused. Some lawyers tell us that the idea of proxy

consent is inadmissible. This means that in law the parents are the trustees for the child, but the general law of trusteeship is that trustees are entitled to consent only to those things which they perceive as being for the benefit of the ward. Therefore, therapeutic research, i.e., experimental employment of procedures for the benefit of the child, even if they are innovative, is permissible.

But in nontherapeutic research—that is to say, the use of procedures not of direct benefit to the individual infant who is being experimented on—the parents as guardians of the child have no standing to give consent. So the question of how any kind of experimental pediatrics involving nontherapeutic procedures can be authorized is legally as well as politically a thorny problem.

The whole question of the stages of embryonic and fetal development is one of great complexity. The ethical issues that arise regarding either abortion or experimentation change as the months pass.

The legal standing of a fetus as far as the courts are concerned is fairly clear. The courts on the whole are not prepared to regard fetuses as having any legal standing.

When the matter of fetal experimentation was being debated before the Commission, two groups of people argued that by consenting to an abortion a woman forfeited her right to have a say in decisions about experimentation. One group, composed chiefly of theologians, adopted a punitive attitude toward the women in question. The other group, chiefly scientists, seemed only too happy that the issue of abortion—the fetus—should fall to them as research material.

The Commission's attitude was that a woman should not automatically forfeit her right to a say in a situation of this kind. Presumably, however, if the woman did forfeit that right, the aborted fetus would in some way become a ward of the court or the state.

Scientists see themselves as having been subject to review and judgment by their own colleagues far longer than they have accepted public criticism. It could happen, however, that in due course scientists may be subject to civil action, under either the law of tort or the law of privacy. Citizens are no longer prepared to accept the presumption that the things scientists do under the heading of "research" are intrinsically harmless.

Scientists will continue being entitled to handle those questions about the conduct of research that concern only themselves. But they will also increasingly have to answer the political challenge that they should be required to demonstrate publicly the acceptability of the things they propose to do if those are going to be sanctioned, as well as paid for, by the public authorities.

Public Act 76-276: An Act Concerning Disability of Physicians

Summary

The 1976 General Assembly passed into law P.A. 76-276—An Act Concerning Disability of Physicians. Frederick C. Weber, Jr., Acting President of the Connecticut Medical Examining Board, has distributed to the Society, the component County Medical Associations and to all health-care facilities a “summary” of the new Act’s provisions and what each of the provisions will mean when it is fully implemented. On January 20, 1977, the Council voted to have the “summary” published in the Journal for the information of the membership.

- A. Enlarges the present Connecticut Medical Examining Board by adding:
 - 1. A full-time member of the faculty of the University of Connecticut School of Medicine.
 - 2. A full-time chief of staff in a general care hospital in Connecticut.
 - 3. Two members of the public not connected with medicine, one of whom shall be an attorney admitted to practice in Connecticut.
- B. Locates the Board offices in Hartford. Provides for an Executive Director, appointed by the Commissioner, with the approval of the Board.
- C. Mandates that the Connecticut State Medical Society, any county society, any hospital, or any physician notify the Connecticut Medical Examining Board of any physician who is, or may be practicing medicine without reasonable skill or safety.
- D. Gives the Board the power to discipline a physician unable to practice medicine with reasonable skill and safety for the following reasons:
 - 1. Physical illness
 - 2. Emotional or mental illness
 - 3. Abuse of alcohol or narcotics
 - 4. Illegal, incompetent or negligent conduct
 - 5. Possession, use or prescription of controlled substances or legend drugs, except for proper uses.
 - 6. Misrepresentation or misconduct or concealment of a material fact in obtaining a certificate or license to practice medicine.
 - 7. Advertising relating to the practice of medicine likely to deceive the public.
- E. Allows any person, medical society (county or state), physician, hospital or the Board itself to file a complaint against a physician. Forms will be provided and the complaint must be sworn to under oath.
- F. Requires notice to the physician, and allows him 20 days to respond, after which time the Board reviews the complaint to determine if reasonable doubt is raised.
- G. If there is not reasonable doubt, the Board may dismiss the complaint. If there is reasonable doubt, the Board may investigate the complaint or send it to the County Medical Society where the physician practices for their investigation.
- H. After receipt of the County Medical Society report or the Board report, the Board votes on whether or not to conduct a further investigation. If the Board votes yes, it may require, as a part of the further investigation a physical or mental examination of the physician. If the Board or County Medical Society report recommends no further action, the complaint may be dismissed.
- I. If the final Board report recommends action against the physician, a hearing, in accordance with the Administrative Procedure Act, must be held.
- J. Within 30 days after the hearing, the Board issues its findings of fact and its decision. If it decides that the physician has violated the above criteria, it may:
 - 1. Reprimand the physician;
 - 2. Restrict the certificate of registration, which may include requiring continuing education or practice under supervision;
 - 3. Suspend the certificate of registration; or
 - 4. Revoke the certificate
- K. The Board decision may be appealed.
- L. Provides that the Board’s decision must be forwarded to the physician, complainant, County Medical Society, State Medical Society, and any hospital at which the physician has staff privileges.
- M. Allows the Board to rescind its order at a later date.
- N. Allows the Board’s decision to be admissible in court in a later action, but does not allow the

findings of fact or the contents of the investigation to be admissible: Provides that the hearing itself shall not be open to the public.

- O. Requires annual reporting to the Governor and the General Assembly of statistics re: complaints received, disciplinary actions taken, and recommendations for improvements and changes.
- P. Provides any appropriation to carry out the provisions of the Act.
- Q. Any health care facility which terminates or restricts the staff membership or privileges of any

licensed physician shall notify the Board of such action.

- R. Provides immunity to individuals and/or organizations which make a complaint and/or provide information with respect to a complaint, unless malice can be shown.
- S. Mandates that any health care facility which terminates or restricts the staff membership or privileges of any physician shall within 15 days notify the Connecticut Medical Examining Board of such action.

**Excerpts from
CSMS Position Statement on Licensure of Allied Health Personnel
Prepared by
Connecticut Joint Practice Committee**

There is a great discrepancy among hospitals, medical and nursing schools, colleges, technical schools, and non-hospital health agencies about titles, functions, tasks, and definitions of allied health roles. Job descriptions are often inadequate in describing actual tasks. Technology and educational curricula develop so fast that it is impossible to keep abreast of job descriptions and new credentials. When legislators enter the complicated and sensitive field of licensure in response to pressure groups, the resulting inflexibility and difficulty of repeal contribute to the confusion and cost-inefficiency. Reliance on non-expert counsel can result in expedient rather than sound legislation.

Neither indiscriminate proliferation nor elimination of licensure is rational. Some socially more appropriate questions to answer in the issues of licensure might be:

1) Is the specific health service essential to the public good?

2) If deemed essential, how hazardous is mediocre or poorly skilled performance of this service?

3) Within the health care field are there established, widely recognized and widely accepted standards for

performance upon which to base the licensure of this service?

4) Is the offered service unique to the category of worker for whom new licensure is provided?

5) Are there effective mechanisms, other than licensure, available for the protection of the public interest to assure that performers of the service meet at least minimum accepted uniform standards?

6) Will the service be improved by the introduction or elimination of a licensing process?

Licensure is in the public interest if a service is considered essential to the public's good, if poor performance is hazardous, and if individuals are unable to safeguard themselves or choose alternative services.

It is recommended that the present "moratorium" on new licensing and modification in licensing of health care workers should be extended.

Kenneth F. Brandon, M.D.
Chairman, CSMS Committee
on Allied Medical Services

Approved by
CSMS Council, 1/20/77

Month in Washington

The Carter Administration has fired the first torpedo in its opening battle against escalating health care costs by asking Congress to approve a "permanent hospital cost containment system" that would cover all hospital operations, private as well as governmental.

Recommended in the revised budget prepared by the Administration is a limit of about 9 percent on increases in reimbursement for operating costs per admission for each hospital for the fiscal year that starts Oct. 1.

Other features of the plan "to contain the continued rapid and disturbing rise in the cost of health care" included:

- **waiver for states with acceptable hospital rate review programs.
- **separate controls on hospital outpatient departments, to encourage alternatives to inpatient care.
- **federal programs to encourage additional cost containment activities such as second opinion before surgery, pre-admission review for non-emergency hospital care, etc.
- **monitoring for federal compliance, primarily using data already reported by hospitals for other programs, such as Medicare and Medicaid. Hospitals found in violation of reimbursement ceilings in any year could "repay" excesses by reducing charges or reimbursement increases in future years. Civil and criminal penalties would be included to combat fraud and abuse.

Under the proposal, the Health Education and Welfare Department Secretary would appoint a National Advisory Committee "of broad representation" to help determine future trends in spending for hospital care.

The program would be directed by the Health, Education and Welfare Department and would begin with a directive from Congress to establish limits on annual rates of increase in hospital reimbursement from all payors, beginning in fiscal year 1978, after consultation with the health industry and the public. The program itself would be administered in large part by the hospitals and private third party payors, according to HEW.

The plan is to evolve a more permanent cost containment program later. This plan would remain in effect "until absorbed by reimbursement provisions of a comprehensive national health insurance plan."

Savings of such a program were estimated to be about \$1 billion the first year, rising to \$5.5 billion in 1981.

The cost containment plan, which hasn't been fully worked out yet, will be submitted to Congress shortly for legislative approval following meetings with such interested outside organizations as the American Hospital Association, the American Medical Association and Blue Cross, HEW Secretary Joseph Califano told reporters at the HEW budget briefing. Other organizations notified to meet with HEW included the Health Insurance Association of America and the Federation of American Hospitals.

Despite the sweeping scope of the proposal, covering private expenditures as well as those under federal programs, Califano denied the plan represented a return to the wage-price freeze system of several years ago. He insisted the new plan was a different animal.

Asked why physician fees were not covered, the HEW Secretary said his department is taking "one step at a time." Califano said "we will be looking at that to see what should be done." There has not been enough time to move in this area with a proposal that could work and that would be fair to the people involved, he said.

The hospital cap is no cinch to clear Congress which has been leery in recent years of wage-price freeze plans and which last year refused even to consider President Ford's recommendation for caps on Medicare reimbursement increases for physicians and hospitals. A key factor could be the position of organized labor which is vigorously opposed to federal wage-price restraints. In addition, health care lawmakers have been considering their own proposals to curb the costs of Medicare-Medicaid including a prospective reimbursement plan for hospitals.

A ceiling on hospital cost increases is "an essential prerequisite to a future national health insurance program," said Califano. . . . "The cost containment program represents the first step in making national health insurance financially feasible."

Under the plan, no hospital could increase its overall level of charges by more than the negotiated and federally sanctioned ceiling.

Califano said that if hospitals raise charges without economic justification before the program goes into effect "it may be necessary for the legislation to have sufficiently retroactive impact to nullify the benefits of such improper conduct."

John Alexander McMahon, President of the American Hospital Association, immediately declared that any program that sets an arbitrary limit on one segment of the economy while ignoring the rest is "inequitable, unworkable and may well be counterproductive."

Asserting the flat opposition of the AHA to the proposal, McMahon said a cost containment plan must take into account wage and price increases beyond the control of hospitals as well as the individual circumstances of each institution.

Recent statistics show that food and fuel prices are rising faster than those for health care, according to the AHA President. "Hospital charges have gone up as a direct response to the public's need for access to quality health care," he said.

The Federation of American Hospitals called the plan "unrealistic and unfair," John A. Bradley, FAH President said, "The goal is laudable but legislation imposing controls on prices without controls on wages and supplies is unrealistic and unfair. The proposal is a retread of President Nixon's Phase IV control program and it is inconsistent with President Carter's policy against wage-price controls as well as his desire to reduce the growth of government."

Bradley said an arbitrary cap on reimbursement "would be a government directive to hospitals to sacrifice the quality of care."

He added: "It is disappointing that government has not addressed the causes of hospital inflation, particularly the malpractice problem. Under an arbitrary cap, a hospital could find itself in the ludicrous position of having to restrict the number of tests a physician may order."

The Carter Administration has announced plans to write off the military medical school as a \$50 million mistake.

Defense Secretary Harold Brown said: "The University of Health Sciences is to be closed, its current students placed elsewhere in scholarship programs and its facilities put to other use. Physician needs of the military services can be satisfied more economically over the long run by direct recruitment. The 1978 budget can be reduced by \$14 million."

The surprise decision came as the military medical school was midway through its first year of operation with 32 students and construction of a building was well along on the grounds of the Bethesda Naval Medical Center near Washington, D.C.

The school has been opposed by the American Medical Association since Congress considered the proposal in 1972. In the interim it also has come under severe attack from various study commissions and lawmakers as an inordinately expensive method of producing relatively few physicians for the armed services.

Congress may move to reverse the Administration's decision although the prime mover for the school—

former Rep. F. Edward Hebert (D-La.), Chairman of the House Armed Services Committee—is no longer in Congress. There is strong backing for the school on both committees, but it has not been tested to date by a forceful presidential move to kill the facility.

The defense announcement was part of a series of policy proposals contained in President Carter's revised budget for fiscal 1978.

The dilemma facing the Carter Administration on national health insurance was bluntly stated by the Congressional Budget Office in its annual report. A plan fully financed by taxes, as Labor proposes, would use most of the money available for new programs "and would most likely require compensating reductions in other federal programs or tax increases above current policy levels." The budget office, which helps guide and determine Congress' spending and legislative plans, put the 1982 cost of such an NHI plan at a minimum of \$108 billion.

Alice Rivlin, Director of the Budget Office which functions in relation to Congress much as the Office of Management and Budget functions in relation to the Executive branch, said a strong economy could leave room for new federal programs adding up to an additional \$50 billion of spending a year over the next several years. However, a wholly tax-financed NHI plan would swallow this and more, if no cost-sharing devices were featured such a plan—as urged by organized Labor—"could add from \$168 billion to \$200 billion to federal health expenditure by fiscal year 1982," said the Budget Office report. In contrast, the report continued, "a compulsory employment-based, premium-financed plan with cost-sharing (such as the AMA proposal) might increase federal spending by as little as \$15 to \$20 billion in 1982."

The government is moving on two fronts to encourage the use of physician extenders (PE's) in rural areas.

The Social Security Administration has launched an experimental program to reimburse physicians for "independent" medical services provided Medicare beneficiaries by physician extenders. Previous policy had been to reimburse physicians for PE Medicare Part B services only those "incident to" a physician's services and performed under the direct supervision of the physician. The new policy will permit payment for the independent services of physician's assistants, nurse practitioners, medex and similar non-physician health care providers. The reimbursement will be made only to a physician extender's employer, not to the PE directly.

The President's Page



This will be my last appearance on the President's Page. I would like to use this opportunity to summarize what I have been trying to say for the past year.

The first item is that the practice of medicine is being challenged in many divergent areas by many different groups. It is vital that these challenges be met by a unified medical practice. Unification does not mean agreement on all matters. It does mean, however, that every individual practitioner has the same voice and opportunity as each of his peers in determining policy and that policy once established is that of the majority, and because it is the judgment of the majority it will be supported by all. Fragmentation of the profession into small groups, each determining its own policy will serve only to dilute the voice of medicine as a whole. I have argued before that the AMA does offer us this opportunity to unite. It is set up along completely democratic lines and can present the policy of medicine if only we would all belong and insure that it therefore did represent all of medicine. The price is small and in a real sense we can not afford not to belong.

What then are our goals, once having determined to band together to achieve them? First and foremost should be a dedication to preserve the quality of medical care. This is a position that can accept no compromise. We must preserve the status of the physician as being the sole judge of medical care. In doing this it is necessary that our judgments be made on the basis of fact and not on that of convenience. In brief, we must preserve our status and maintain the highest principles in so doing. This action seems clear-cut to me.

The second of our goals is not as easy or as obvious. This has to do not with the quality of care but rather with the delivery of care. Here, differences of opinion become much more pronounced. There are those who advocate taking a hard line, namely that we provide good medicine as we practice it now and all changes must be resisted. There is a contrary opinion that our present method of delivery of health care is outmoded and requires complete restructuring. I would offer that the best position lies somewhere between the two extremes. We must recognize the need for a health care system which will provide for our entire population. The solution of this problem is not easy. The effort to find it brings us into conflict with many non-medical groups who would like to provide their answer for us. We must be able to share our thoughts and our interest with such groups. We must accept the concept that the ramifications of the problem requires the expertise of all of us but here again I believe most of us would like to solve the problems within the overall framework of our present system.

And so I close as I began with the plea for unity in attempting to solve these matters.

Hilliard Spitz, M.D.
President

Reflections from the Dean's Office

Robert U. Massey, M.D.

Twenty years ago it was not uncommon for prescriptions to be written in Latin. It was often bad Latin written illegibly, but the practice served to mystify the patient and to preserve a secret bond between physician and pharmacist. Today the bottle of pills bears a generic label, even though the prescription may still carry some vestigial medieval symbols.

Clearly there has been a change in our notions of what we are to tell patients about their illnesses and our plan of treatment for them. Sociologists can give several reasons why patients expect to know more about health, disease, and treatment in 1977 than they did in 1937. In fact, physicians are prepared to tell them more. Medicine rests more upon science and less upon empiricism now than it did forty years ago, and science does not have to hide behind mystery the way empiricism may. Our outcomes are better and more predictable, our treatment more rational and therefore easier to explain.

Why tell our patients anything? An eminent physician once told me of an incident which took place when he was a house officer. The professor was making rounds and stopped to ask an elderly patient how long he had been in the hospital.

"Five or six days," he answered.

"What do they say is wrong with you?"

"I don't know," the man answered, "No one has said."

"Who is your doctor?"

"That man there with you—I don't know his name."

The professor took the young resident aside and said, "If we ever have another conversation like this on your service, you can pack your things and leave!"

Physicians share information with their patients, discuss diagnostic tests, review various kinds of treatment, and talk of outcomes and risks for three reasons. The first is the recognition of an ethical obligation to do so. The second is because this sharing of knowledge is a part of treatment. The third is because there is a legal requirement to inform the patient in order to obtain consent to proceed.

Paul Ramsey¹ suggests that the relationship between patient and physician is better described as a *partnership* than a *contract*. He speaks in the preface to his book *The Patient as Person*, of responsibilities to a covenant as being at the heart of our relationship

to one another, and declares that "the practice of medicine is one such covenant." He asserts that man is sacred and that "The sanctity of human life prevents ultimate trespass upon him even for the sake of treating his bodily life."

Before the patient can enter into the partnership of care he should know the terms to the extent of his understanding. More is implied in the covenant than truth telling, but establishing trust through sharing of information is the beginning of meeting the obligations of the covenant.

The patient who knows about his illness, and who may have helped to choose his therapy, who has been told of the risks and expected outcomes, is a better patient. Doctor means teacher, and the teacher teaches even when the pupil is not eager to learn. In deciding about treatment, or whether to treat at all, the partners must be sure that they share the same information and have common goals in view. It may happen that restoration of health is not the patient's goal; the physician as teacher now becomes more important than the physician as healer. Illness is a complex matter and physician and patient must share their knowledge, insights, intuitions, and sometimes prejudices if the partnership is to make any progress.

Finally, the law requires that the patient be informed of the procedures to be used upon him, the risks involved, the expected outcome, and the available alternatives. He must retain his right to choose. As in other situations, the law defines the limits; it does not compel the process. I think the law in this instance rests on the first reason, upon ethics, not the second. The legal concept of informed consent is only 63 years old, originating from a 1914 case wherein "medical battery was defined as the intentional touching of a patient's body without his consent."² It is an extension of the covenant.

Of course, there are exceptions. The covenant requires that we not hurt or cause despair by ill-timed disclosure of dreaded information. We may believe that no good would be served by discussing prognosis now, and that recovery might be delayed if the patient were made more anxious or more uncertain. We may hold back, note the exception to our rule, and prepare the patient, and ourselves, to face the issue later.

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EDITORIALS

Abortion and the Language of Feeling

Abortion has always been a fact of human life, whether or not it was legally or morally permissible, or medically safe. With the many unpredictable, impulsive and passionate elements in human nature, pregnancy terminations will continue to be needed in spite of improved methods of contraception. The new abortion laws provide women with the option of abortion during the first two trimesters of pregnancy, but in spite of the legal accommodation, the moral-ethical consequences of abortion continue to excite an emotional response.

When a subject as controversial as abortion is discussed, the vocabulary used often illuminates the strong emotionality with which it is invested. An issue which strikes to the heart of feelings about sexual morality and the sanctity of life, it has tended to polarize opinions. These are often cleverly expressed in emotion-laden words and slogans, a language of feeling rich with innuendo and powerful in its capacity to stimulate sympathetic response. "Abortion is murder," they claim. Murder! Is there any equally dramatic term which could possibly counter the thundering finality of "Murder?"

"Save the innocent fetus," they plead. Innocent of what? Is a fetus an entity capable of activities which could demonstrate either innocence or guilt? In spite of counter-claims that the innocence of the fetus is at best a questionable criterion, the use of the term has made its impact. The word "innocence" keeps ringing in the mind's ear in tandem with its antonym "guilt."

Anti-abortion groups like to designate their stand as "pro-life," a most laudable position. Members of the opposition are "pro-abortion." They are not "pro-lifers," so by implication they must be "anti-life."

Who stops to think whether that conclusion logically follows? Although it has not really been stated explicitly, the idea has been planted and the point is made. Pro-lifers fervently support the "right to life"; pro-abortion groups support the "right to choose." Beside the "right to life," the "right to choose" becomes a feeble imperative.

In a recent study conducted by researchers at the University of Connecticut School of Medicine in Farmington, Connecticut, only one out of 141 Connecticut OB/GYNs interviewed embraced the title "abortionist" as one having a positive connotation. This is not surprising. When they were in medical school, abortion was illegal, and their professional training emphasized their responsibility to work within the moral framework of society and its legal system. In this context abortion was both illegal and immoral. An obstetrician who earned the title "abortionist" was held in disgrace. With legalization, the abortionist is an OB/GYN in legitimate practice.

The law has changed, but has the moral climate kept pace? The term "abortionist" appears to have retained some of its original taboo. Legal changes alone do not alter firmly held attitudes. Physicians still do not like to perform abortions, and still do not like to regard themselves as "abortionists." To accommodate their negative feelings about this term, abortion is now called "pregnancy termination." Garrett Hardin described women's earlier no-choice situation as "mandatory motherhood" and "compulsory pregnancy"; these conditions may now be exchanged for an "elective termination." The use of language to depersonalize a procedure is well illustrated when physicians "terminate a pregnancy" rather than "abort a fetus." Depersonalization establishes the distance necessary to protect feelings.

Sometimes silence is equally eloquent. Many OB-GYNs practice in a self-imposed isolation of silence,

rarely discussing sensitive ethical issues with others in their field of specialization. This may be one of the numerous ways in which physicians protect their personal autonomy (which they value highly) from possible erosion from outside influence. Deliberate detachment from external pressures is a strong indication that abortion is a very personal and sensitive issue which for many physicians remains incompletely resolved.

Regardless of their former disposition toward abortion, and regardless of their religious affiliation, OB/GYNs have been profoundly affected by the change in the abortion law. In the past, almost all of them have had patients who have wanted an abortion for compelling reasons which may have stirred their deepest compassion, yet they were powerless to help these patients. With legal restrictions removed, many physicians have found it necessary to review their personal attitudes in order to establish their professional responsibilities regarding abortion. Their initial positive reaction to the legislation has frequently given way to the realization that legality notwithstanding, their personal ethics continue to exert a strong influence on any medical decisions they make.

Listening to the rhetoric, we hear an eloquent message in the selective use of language in the discussion of abortion. Strong feelings are being expressed. The use of the language of feelings is evidence that ethical considerations continue to trouble physicians, as well as others involved in the abortion issue.

Agnes Thomas,
Research Assistant
Department of Psychiatry

University of Connecticut Medical School
Farmington, CT

Medicredit—1977

Meetings of the AMA House of Delegates usually are stimulating, enlivened by at least one or two controversial resolutions. At the December 1976 meeting in Philadelphia, some zest and interest were provided to an otherwise lack-luster meeting by a surprising concerted opposition from several states against the AMA Medicredit bill now called the "Comprehensive Health Care Insurance Act of 1975."

My comments are based upon the report of the Board of Trustees and the debate and vote of the House of Delegates. Except for minor changes, the bill contains the same provisions and principles of the original AMA 1970 Medicredit bill. The report, in this issue, deserves to be read by every CSMS member.

Whereas opposition to Medicredit in the House in the past has been minor and sporadic, at this meeting there was a seemingly organized, prepared assault by several states, opposing support of any national bill in Congress, including the AMA's. The Louisiana delegation spearheaded the opposition. It argued that any national health bill would lead to socialism as exemplified in Britain, and would lead here also to the same sort of economic disaster being suffered in Britain.

The Nebraska, Illinois, South Carolina and New Mexico delegations introduced similar resolutions opposing any national health plan, including the AMA's. A resolution by New England, however, endorsed the AMA bill designed "to preserve the right of a patient to have free choice of physician and the right of a physician to choose to serve the patient."

The Council on Medical Service, an important committee made up of members of the House with no members from the Board of Trustees, in an independent study recommended the report. It held that there "was no valid reason for withdrawing support of the Comprehensive Health Care Insurance Act (HR 6222) . . .," that a "complete about-face by the Association at this point . . . may seriously impair the Association's credibility and cast doubt on the sincerity of this House's past actions." It concluded that "The AMA must continue to sponsor a national health insurance bill in Congress designed to aid in the financing and delivery of health care through the private insurance industry with a minimum of government interference. Without such a bill in the 95th Congress, we will be talking only to ourselves."

The reference committee after a long, and at times stormy hearing with no time limits as to testimony, recommended to the House adoption of the Board of Trustees report. It stated that the AMA bill's principles had been debated before the House for some years and its provisions repeatedly endorsed. It answered the few specific criticisms as incorrect in important details.

In spite of exhaustive testimony before the reference committee, the opponents carried their case to the floor of the House by a procession of speakers, again led by Louisiana. Amendments were introduced, hopefully to delay or divert attention from the main issue. One amendment by Louisiana would have the AMA carry on an intensive national PR program to educate the American people as to the dire consequences of any national health insurance bill, with a fiscal estimate that it would cost the AMA \$5,000,000. to \$5,582,500. A surprise endorsement of the report on the floor by the Texas delegation, traditionally "conservative," spelled its adoption. As its spokesman stated, "Texas does not want NHI, but we

do not think the specter of NHI will be driven away (by an AMA vote against it)."

By a vote of 181 to 57, the House voted to reintroduce the AMA bill in the 95th Congress. The bill "embodies the principles approved by this House and represents a viable mechanism to advance the Association's views on the subject."

The vote, however, represents more than a vote on HR 6222; it demonstrates what is becoming an increasing dichotomy in the profession and AMA House of Delegates between two philosophies in reaction to governmentally-sponsored legislation, possibly among Connecticut physicians. Though I am reluctant to use labels, I again would divide reaction to such issues as liberal, moderate, and conservative—admittedly simplistic.

We can eliminate the influence of the few liberals among practicing physicians. I have not yet met any practicing physician so liberal as to advocate a national health program similar to that in Britain or Sweden. Even those physicians who have felt that government should be used to promote social justice have been turned off by inefficiencies and even failures of governmental health programs in the Great Society era. Academia is beginning to realize that government grants have their price, e.g., recent federal legislation mandating admission of American foreign-trained students to medical schools as the price of capitation financial grants. Traditional academic freedom is at stake here. So even academia may join the anti-Washington, antigovernment, antibureaucracy American consensus.

But it is this increasing dichotomy between the so-called moderates and conservatives, as epitomized in our national AMA House of Delegates, that is potentially dangerous to unity in the profession particularly at a time when it is imperative. Though both agree, in varying degree, in their distrust and dislike of political interference in the delivery of health care, they disagree in how to react to the avalanche of health care bills introduced in Congress and legislatures. The moderates believe in being in on the ground floor in the legislative process—to influence, modify, change, and even oppose bills at their source. If bills become law, they continue to police HEW in its formulation of regulations which have all the authority of law. They recommend participation by physicians in the boondocks in the operational process.

The conservatives, however, not only oppose bills while they are being considered and formulated, but throughout the entire process, including the operational phase. Some advocate no cooperation, even active disruption. In judging from the results and failures of recent health governmental programs even

here, let alone Britain, they do have some justification for their position.

The two camps wholeheartedly approve the AMA's going to the courts to challenge both laws and regulations, even at great expense. We in Connecticut have joined the AMA in defense against the FDA charge. We all agree that at stake here is the historic and traditional concept of our profession. And this is the ideal toward which we in the profession should strive—recognize that differences of opinion in our profession are natural, bring them up in our organizational meetings, discuss them fully, vote on them by democratic procedure, and after voting unite against potentially more serious dangers outside the profession. We must recognize the honesty and sincerity of diverse opinions.

It is in this spirit that our delegation, which voted with the majority in Philadelphia, is introducing the AMA bill to our own House of Delegates in April so that the delegates may discuss it and report their opinion by a vote. For as Benjamin Franklin said when he signed the Declaration of Independence, "We must all hang together, or assuredly we shall all hang separately."

Fred Fabro, M.D.

Rabies In Connecticut

There has been no rabies in domestic animals in Connecticut since 1949, in fact even in wild animals very little or no rabies has been found in the last ten years except in bats, and in 1976 two foxes were found to be rabid. It has never been found in rodents of any kind in Connecticut—not in rats, mice, squirrels, chipmunks, rabbits, etc. and bites by rodents have never resulted in human rabies and do not call for anti-rabies prophylaxis.

A properly immunized dog or cat is practically immune to rabies and will not transmit the infection. The likelihood of humans acquiring rabies from dogs and cats is extremely remote in this state yet they continue to be the reason for giving the majority of preventive treatments.

Management of Animal Bites

The problem of whether to treat persons bitten or scratched by animals unavailable for examination, is one of the most difficult and perplexing for practitioners since preventive treatment is not without risk

and adverse reactions may at times be serious. The management of such cases is further complicated by the fact that a decision must be made immediately as the longer treatment is postponed, the less effective it becomes. Whenever possible, it is advisable to consult with and share the burden of such decisions with local or state health officials.

There has been no human death from rabies in Connecticut since 1932. In the last 30 years ten persons in Connecticut have been bitten by rabid animals. Eight of these by bats, one by a fox and one by a skunk. All were given antirabies treatment and none developed the disease. Post-exposure prophylactic treatment is, however, not entirely effective and rabies has occasionally developed in humans who had received such treatment.

Prophylactic Treatment

The wound should immediately be thoroughly cleaned with soap and water and a tetanus booster may be given. Rabies can be transmitted through bites and requires saliva. Scratches not contaminated with saliva are unlikely to transmit the infection.

If the biting animal cannot be found and belongs to a species likely to be infected with rabies, a combination of passive and active immunization as early as possible is recommended.

Duck Embryo Vaccine

Duck embryo vaccine (DEV) is now the preferred treatment. It is a killed vaccine, supplied as 1 ml single dose vials with a diluent ampule.

Twenty-three 1 ml doses should be given as 21 daily doses. Two boosters should be given 10 and 20 days after termination of the treatment. The sites are the abdomen and the lower back and rotation of sites is recommended.

Local reactions to preventive treatment with DEV are common and include pain, erythema, and induration. Systemic symptoms including fever and malaise, occur in about 30 percent of the cases, usually after one week. Anaphylaxis develops in one percent of those receiving DEV. Neurologic reactions have become rare with DEV. If neurologic reactions develop, the treatments should be discontinued.

Rabies Immune Globulin (RIG)

This is supplied in 2 ml and 10 ml vials for pediatric and adult use. RIG is administered only once at the beginning of the treatment. Half of it should be infiltrated around the wound and the rest given intramuscularly. It rarely produces adverse reactions.

Antirabies Serum, Equine (ARS)

This hyperimmune serum is available in 5 ml vials. ARS produces serum sickness in almost half the recipients therefore it should only be used if RIG cannot be obtained within 24 hours.

The Biting Animal

An animal that bites a person should be confined and observed by a veterinarian for ten days. Any illness in the animal should be immediately reported. If there are signs suggestive of rabies the animal should be killed, its head removed and brought as quickly as possible under refrigeration to the State Health Department for examination. If stray dogs or cats are involved, they should be killed immediately and their heads submitted for examination. The same refers to wild animals that bite or scratch.

If the brain is negative for rabies by fluorescent antibody, the person need not be treated. An unprovoked attack is more likely to mean that the animal may be rabid. However, bites inflicted after attempting to feed or handle wild and apparently healthy animals should be regarded as provoked.

Pre-Exposure Prophylaxis

This is advisable only for veterinarians and travelers to areas where rabies is common. It consists of 2 ml injections of DEV given one month apart and a third dose 6 months later.

Protection Against Rabid Animals

People, especially children, should be warned against close contact with wild animals, particularly against handling bats.

Hans H. Neumann, M.D.

Medical Director

New Haven Health Department

CORRECTION

In the article, "Medical Communication Sources for Continuing Physician Education: Used or Unused?" by Dr. Jerome J. Harris, published in the February issue (40-111-114, 1976), the author inadvertently mentioned that Clin-Alert was a U.S. Government-related service. Clin-Alert is and always has been privately owned and operated by Science Editors, Inc. as an unbiased loose leaf service regarding the therapeutic hazards physicians may encounter with presently available drug compounds.

THE PRIMARY SURGICAL TREATMENT OF CARCINOMA OF THE BREAST

A Changing Trend Toward Modified Radical Mastectomy

This study analyses the effectiveness of the Mayo Clinic's trend toward modifying the standard radical mastectomy. The 5-year survival of 873 women treated from 1965 through 1968 by both surgical methods was evaluated. Of the 873, survival of 534 treated by the standard radical mastectomy was 85% with negative nodes and 56% with positive nodes. For the remaining 339 treated by the modified radical mastectomy, survival was 80% with negative nodes and 48% with positive.

The modified radical mastectomy was identical to the standard radical mastectomy except that both pectoral muscles were left intact, with en bloc excision of the axillary contents and the interpectoral nodes of Rotter.

To eliminate "statistical nuisance factors," the 5-year survival of a relatively homogeneous group of 541 was taken from the total 873 to better compare the two procedures. Those from the original total of 873 with one or more of the following characteristics were excluded: 1) Potentially life-threatening, nonmalignant conditions 2) Other nonquiescent malignancies 3) known residual cancer left behind at surgery 4) Lesions fixed to the chest wall 5) Inflammatory breast carcinoma 6) Cancer extending beyond the breast and ipsilateral lymph nodes 7) Biopsy done elsewhere 8) Location of the lesion in the breast unknown 9) Size of the lesion unknown 10) Multiple or diffuse lesions.

In this remaining group of 541, 336 (86%) treated by the standard radical mastectomy with negative nodes survived and 66% with positive. Eighty-four percent of 205 treated by the modified radical with negative nodes survived and 66% with positive nodes.

Patients were followed for a period of five to nine years with all cases available for a 5-year statistical follow-up.

RESULTS OF TOTAL

Axillary nodes

"Axillary node metastasis was a major factor limiting survival, irrespective of the type of mastectomy or characteristic of the primary tumor." Number involved was important. "Survival is significantly better in those with one to two positive nodes than in those with three positive nodes." The 5-year survival for the total group of 873 was 70%-those with negative nodes, 83%; whereas those with positive nodes, 53%. Survi-

val of those with one to three positive nodes was 66% compared with 40% in those with more than three involved nodes. The status of axillary lymph nodes proved to be the single most important determinant in survival.

Size

"In general, the larger the size of the primary tumor, the poorer the prognosis. However, when Nodes were negative, this is less significant than when the nodes were positive." Tumors less than 1 cm in diameters are classified as minimal breast cancer, with the best prognosis. However, metastasis was present in one of every four tumors less than 1 cm. "Although the numbers are small, it seems that patients with positive nodes and the smallest tumors have a poorer survival than those with negative nodes and larger lesions."

Grade

In general, "the higher the grade of malignancy, the greater the number of axillary nodes involved and, therefore, the worse prognosis." Survival of patients with negative nodes was essentially the same with all grades. A decline in survival in lesions with grade 3 and 4 with positive nodes was highly significant, approximately 30%.

Location

This seemed to exert some influence on survival, both for negative and positive nodes. If negative, patients with inner-half and central lesions had a better survival than those with outer-half and central lesions had a better survival than those with outer-half lesions. With positive nodes, survival was poorest in those with centrally located lesions.

Histopathic type

Except infiltrating scirrhous adenocarcinoma of ductal origin, the number with less common histologic types was too small to draw significant conclusions.

Postoperative irradiation

Although the data show that survival was better in those without postoperative irradiation, the authors "urge caution in interpreting these findings." Radiation techniques and use were too varied to make a valid interpretation. Indications for postoperative radiation therapy reflected "the purely arbitrary approach to adjunctive radiotherapy" depending on the surgeon.

Though the numbers reflect a slightly better survival for the radical mastectomy group, when corrected

(continued on page 256)

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185th ANNUAL MEETING
of the
CONNECTICUT STATE MEDICAL SOCIETY
Hartford Hilton Hotel
10 Ford Street, Hartford, Connecticut
April 27, 28, 1977

**COMMITTEE ON PROGRAM OF THE
SCIENTIFIC ASSEMBLY**



MICHAEL J. ESPOSITO

Michael J. Esposito, Meriden, Chairman
D. Norman Markley, Hartford
Malcolm M. Ellison, New London
Frederick I. Fischbein, Middletown
James E.C. Walker, Farmington

Dr. William Richards has notified the Society that after 18 years of devoted service he would like to retire from his position as Executive Director. It will be a difficult job to find a satisfactory replacement. We do want to show our appreciation of "Bill's" efforts and the annual dinner will be planned as a testimonial to him. All members of the Society and their spouses are welcome "dutch treat" at the annual dinner and we are looking forward to a large turnout. Dr. Isadore Friedberg of Newington will be inaugurated as your new president at the dinner.

The scientific program on Thursday should be an excellent one concentrating on nephrology in the morning with discussions on Calcium Regulation and Nephrolithiasis. The afternoon session will be devoted to problems of the thyroid gland. These subjects should be of interest to all physicians whether in the field of medicine or surgery and the Committee on the Program for the Scientific Assembly is to be commended for its choices. Thursday will end with the various section meetings. This day should have something in it for everybody. We look forward to a good attendance for what should be an outstanding scientific day.

HILLIARD SPITZ

GENERAL INFORMATION
READ CAREFULLY

A MESSAGE FROM THE PRESIDENT

The 185th Annual Meeting of the Connecticut State Medical Society will be held on April 27 and 28, 1977 at the Hartford Hilton Hotel. It will be a 2-day affair again with the House of Delegates Meeting on Wednesday and the Annual Dinner of the Society Wednesday night. Thursday will be devoted to the educational program of the Society.

An effort is being made this year to streamline the program of the House of Delegates. It is planned to start the reference committee proceedings after only the most necessary ceremonies and the goal will be to finish all reference committee hearings before breaking for lunch. If necessary lunch will be delayed to accomplish this purpose. This will allow all the reference committees to complete their deliberations during lunch and so not prolong the waiting period for considering committee reports in the House. Also in the interest of saving time and getting the House back to work, no formal program is scheduled during lunch. In order to keep to this schedule it is imperative that delegates arrive promptly in the morning.

REGISTRATION

The registration desk will be located on the mezzanine floor and everyone attending the meeting is requested to register. There will be no charge for registration and all members of the Society will be given a guest luncheon ticket when and only if they register.

PARKING

There are ample parking facilities at the hotel and in the surrounding area.

TELEPHONE

Telephone messages will be received at Hartford 249-5611.

LUNCHEON

Luncheon will be served in the Terrace Room on the mezzanine floor on April 28th and **ALL MEMBERS OF THE SOCIETY REGISTERING WILL BE THE GUESTS OF THE SOCIETY. PLEASE REMEMBER A LUNCHEON TICKET WILL BE GIVEN TO MEMBERS ONLY IF THEY REGISTER.**

HOTEL ACCOMMODATIONS

Persons who wish to remain overnight should make reservations not later than two weeks prior to opening date of the meeting. Reservations will be held until 6:00 P.M. on the day of arrival, unless later hour is specified. Please indicate in your letter that you are attending the Connecticut State Medical Society meeting. Your letter should be directed to the Front Office Manager, Hartford Hilton Hotel, 10 Ford Street, Hartford, Connecticut.

ANNUAL DINNER

The Annual Dinner will be held at the hotel on Wednesday, April 27, 1977. The social hour will be at 6:30 P.M. and the dinner at 7:30 P.M. All persons attending the dinner will be the guests of the Society at the social hour. Your reservations for dinner should be sent in as soon as possible to the CSMS office.

PROGRAM

The scientific portion of the Annual Meeting will be concentrated in one day, April 28, 1977. The general program will be held in the Capitol Ballroom between 10:30 and 4:00, and section meetings will be held in the morning at 8:30 A.M. and in the afternoon at 4:00 P.M. in the rooms listed in the program.

EXHIBITS

All the exhibits will be located on the mezzanine floor. Physicians should take advantage of the opportunity to review what is new and timely by visiting the commercial exhibits.

ALL ACTIVITIES WILL TAKE PLACE AT THE HOTEL
UNLESS OTHERWISE INDICATED.

SPECIAL NOTICES
CONTINUING MEDICAL
EDUCATION CREDITS

AMA PHYSICIAN'S RECOGNITION AWARD

The Yale University School of Medicine has accredited the scientific program of the Society's Annual Meeting for Category One Credit toward the AMA Physician's Recognition Award. Credit is granted in this category on an hour-for-hour basis.

**AMERICAN ACADEMY OF FAMILY
PHYSICIANS**

The Commission on Education of the AAFP has accredited the scientific program of the Society's Annual Meeting for 5-1/2 hours of prescribed credit for the general lectures and the family practice section meeting, and one hour for elective credit for each lecture attended which is presented by the individual specialty sections of the Society.

HOSPITAL RESIDENTS, INTERNS AND MEDICAL STUDENTS ARE CORDIALLY INVITED TO ATTEND THIS MEETING.

**ANNUAL MEETING OF THE
HOUSE OF DELEGATES**

WEDNESDAY, APRIL 27
CAPITOL BALLROOM **MEZZANINE**

Presiding:

TIMOTHY F. NOLAN, *Greenwich, Speaker of the House*
DAVID A. GRENDON, *Sharon, Vice-Speaker of the House*

- 7:30 REGISTRATION OF DELEGATES—Mezzanine Floor
Continental Breakfast for Delegates and Official Guests
- 8:30 CALL TO ORDER
OPENING SESSION
REFERENCE COMMITTEE HEARINGS
- 1:15 LUNCHEON—Terrace Room, Mezzanine
- 2:30 CALL TO ORDER—Capitol Ballroom
FINAL SESSION
- 6:15 ADJOURNMENT

ANNUAL DINNER OF THE SOCIETY
WEDNESDAY APRIL 27

featuring

TESTIMONIAL TO WILLIAM R. RICHARDS,
RETIRING EXECUTIVE DIRECTOR

TERRACE ROOM MEZZANINE
Social Hour 6:30 P.M. Dinner 7:30 P.M.



WILLIAM R. RICHARDS
Executive Director, CSMS

PROGRAM

Presiding: HILLIARD SPITZ, New London

- PRESENTATION OF GUESTS AND DELEGATES
FROM STATE MEDICAL SOCIETIES
- INAUGURATION OF INCOMING PRESIDENT,
ISADORE H. FRIEDBERG, NEWINGTON
- INTRODUCTION OF WILLIAM R. RICHARDS,
NEW HAVEN
- ADDRESS OF EXECUTIVE DIRECTOR
- PRESENTATION
- ADDRESS OF THE PRESIDENT

SECTION ON PSYCHIATRY

8:30 A.M. Room 424

President: Herbert S. Sacks, Westport

Secretary: Earle L. Biassey, Stratford

THE USE, NON-USE AND MISUSE OF PSYCHOTROPIC AGENTS IN THE
TREATMENT OF ANXIETY STATES IN CLINICAL MEDICINE

GEORGE L. COHN, NEW HAVEN, CONNECTICUT; Associate Pro-
fessor of Psychiatry and Medicine, Yale University School of
Medicine

SECTION ON PULMONARY DISEASES

9:30 A.M. Rooms 408-412-416

President: Lester J. Krasnogor, Stamford

Secretary: Arthur Kotch, Danbury

9:30 BUSINESS MEETING

10:00 NEWER DRUG THERAPY IN ASTHMA

M. HENRY WILLIAMS, JR., NEW YORK CITY; Professor
of Medicine, Chief, Department of Pulmonary Dis-
eases, Albert Einstein College of Medicine

11:00 THE BETA-RECEPTOR (NORMAL FUNCTION AND THE BETA-
BLOCKADE THEORY)

STUART M. BROOKS, CINCINNATI, OHIO; Chief, Clinical
Studies Division, Department of Environmental Health
and Medicine, University of Cincinnati Medical Center

12:00 PANEL DISCUSSION

12:30 INTERMISSION TO VISIT EXHIBITS

1:00 LUNCHEON

AFTERNOON SECTION PROGRAMS

SECTION ON ALLERGY

4:00 P.M. Studio A

President and Secretary: Robert DeBernardo, Bridgeport

ASPIRIN SENSITIVITY

GUY SETTIPANE, PROVIDENCE, RHODE ISLAND; Assistant
Professor, Brown University

SECTION ON ANESTHESIA

4:30

Holiday Inn

Morgan Street, Hartford

President: Ranald J. M. Steven, West Hartford

Secretary: Raymond E. Bradley, Jr., Woodbridge

4:30 BUSINESS MEETING

5:30 RALPH M. TOVELL MEMORIAL LECTURE

GUEST SPEAKER: JAMES F. ARENS, JACKSON, MISSISSIPPI;
Professor and Chairman of Anesthesiology, University
of Mississippi Medical Center
Center

SECTION ON EMERGENCY MEDICINE

3:30 P.M. Room 404

President: Edward R. Browne, Willimantic

Secretary: Allan A. Brandt, Milford

PANEL ON EMERGENCY MEDICAL SERVICES A MEDICAL PROGRAM OF IMPORTANCE TO COMMUNITIES AND PHYSICIANS

Moderator: Edward R. Browne, Willimantic

EMS SYSTEMS: WHY HAVE THEM?

COSTAS LAMBREW, Chairman, Department of Medicine,
State University of New York at Stonybrook

ROLE OF THE EMERGENCY PHYSICIAN IN SETTING NEW STANDARDS
OF EMERGENCY CARE

ALLAN A. BRANDT, Chief of Emergency Department, Mil-
ford Hospital; Member, Task Force on Emergency Cardiac
Care, Connecticut Heart Association

THE DEVELOPMENT OF ADVANCED LIFE SUPPORT ON SCENE IN
CONNECTICUT

JOSEPH ROBERT ANTHONY, Chief of Cardiology, St. Mary's
Hospital, Waterbury

THE STATUS OF EMS SYSTEMS IN CONNECTICUT

DOUGLAS LLOYD, Commissioner of Health, State of Connecti-
cut

PRESSING PROBLEMS WHICH FRUSTRATE THE IMPLEMENTATION OF
EMS

GERALD O. STRAUCH, Chairman, Connecticut Committee on
Trauma of American College of Surgeons; Vice-Chairman,
Connecticut Advisory Committee on Emergency Medical Ser-
vices

LEGISLATIVE AND GOVERNMENTAL SUPPORT OF CONNECTICUT
EMS SYSTEMS

SENATOR ANTHONY CIARLONE, Chairman, Committee on Pub-
lic Health and Safety, Connecticut General Assembly

DISCUSSION

SECTION ON FORENSIC MEDICINE

12:30 P.M. Rooms 436-440

President: Daniel W. Benninghoff, Greenwich

Secretary: G.S. Gudernatch, Sharon

LUNCHEON (Dutch Treat)

BUSINESS MEETING

SECTION ON GASTROENTEROLOGY

4:00 P.M. Room 408

President: Robert M. Vogel, Orange

Secretary: Raphael D. Schwartz, Danbury

ACUTE PANCREATITIS

ANDREW WARSHAW, BOSTON, MASSACHUSETTS; Associate
Professor of Surgery, Harvard Medical School; Attending
Surgeon, Massachusetts General Hospital

SECTION ON NEUROSURGERY

3:30 P.M. Washington Room

President: Edwin H. Mulford, Norwalk

Secretary: Donald W. Cooper, New London

BUSINESS MEETING

PRIVATE PRACTICE OF NEUROSURGERY IN CONNECTICUT

EDWIN H. MULFORD, NORWALK

SECTION ON OBSTETRICS AND GYNECOLOGY

4:00 P.M. Room 424

President: Philip G. Dennen, Waterbury

Secretary: Richard F. Jones III, Hartford

CHALLENGES IN MODERN OBSTETRICS

LAURENCE E. LUNDY, SPRINGFIELD, MASSACHUSETTS; Chief,
Department of Obstetrics and Gynecology, Bay State Medical
Center

SECTION ON OPHTHALMOLOGY

4:00 P.M. Rooms 436-440

President: David W. Parke, Meriden

Secretary: Stanislaw A. Milewski, Manchester

EDUCATIONAL PROGRAM

BUSINESS MEETING

DINNER

SECTION ON ORTHOPEDICS

3:00 P.M.

Hunt Memorial Building
230 Scarborough Street, Hartford

President: Martin L. Karno, New London

Secretary: John D. Haugh, Hartford

RECONSTRUCTION OF UNSTABLE KNEE

ARTHUR ELLISON, WILLIAMSTOWN, MASSACHUSETTS; Sports
Medical Consultant, Williamstown College

JOHN MARSHALL, NEW YORK CITY; Director, Sports Medicine
Section, Hospital for Special Surgery, New York

DINNER TO FOLLOW

SECTION ON PATHOLOGY

4:00 P.M. Room 420

President: William R. Bronson, Hartford

Secretary: David M. Lowell, Waterbury

BRIEF REVIEW OF MORE COMMON NON-HODGKINS LYMPHOMA

IRWIN M. WEISBROT, STAMFORD, CONNECTICUT; Associate
Clinical Professor, Yale University School of Medicine;
Associate Attending Pathologist, Norwalk Hospital

SECTION ON PEDIATRICS

4:00 P.M. Room 416

Chairman: Frederick J. Flynn, Jr., Newington

Secretary: Estelle Siker, Hartford

THE PRIMARY PHYSICIAN AND THE GRIEVING CHILD

MORRIS A. WESSEL, NEW HAVEN; Clinical Professor of
Pediatrics, Yale University School of Medicine, Board member,
Hospice, Inc.

CHILD ABUSE—1977

JOSEPH LEISTYNA, FARMINGTON; Assistant Professor of
Pediatrics, University of Connecticut School of Medicine

SECTION ON PROCTOLOGY

4:00 P.M. New York Room

President: Bernard J. Kaplan, Hartford

Secretary: Sanford Savin, Bridgeport

BUSINESS MEETING

ELECTION OF OFFICERS

SECTION ON RADIOLOGY

4:00 P.M. Buffalo Room

President: Harold D. Batt, New Haven

Secretary: Gerald L. Baker, Hartford

BUSINESS MEETING

SECTION ON SURGERY

4:00 P.M. Ballroom

Chairman: Gerald O. Strauch, Stamford

Secretary: Everitt P. Dolan, Bridgeport

CHARTER BUSINESS MEETING

RECEPTION

DINNER—BALLROOM

GUEST SPEAKER: MARK A. HAYES, NEW HAVEN, CONNECTICUT;
Professor of Surgery, Yale University School of Medicine

TOPIC: WHEN DID WE GET OFF THE TRACK?

SECTION ON THORACIC AND CARDIOVASCULAR SURGERY

4:00 P.M. Boston Room

President: Joseph P. Shea, Bridgeport

Secretary: Allan L. Toole, New Haven

BUSINESS MEETING

ELECTION OF OFFICERS

SECTION ON UROLOGY

4:00 P.M. Room 412

President: Timothy F. Nolan, Greenwich

Secretary: Haik Kavookjian, Jr., Stamford

RADIOISOTOPES—UPDATE IN DIAGNOSIS AND TREATMENT
OF UROLOGIC PROBLEMS

SPEAKER TO BE ANNOUNCED

IMPORTANT—PLEASE NOTE

The following Sections of the Society will not be meeting on April
28, due to various reasons. The programs, dates and time follow:

SECTION ON OTOLARYNGOLOGY

1:30—5:30

Thursday, April 21, 1977

New Haven Lawn Club

193 Whitney Avenue, New Haven

President: Robert S. Rosnagle, New Haven

Secretary: Ronald J. Pimpinella, Torrington

SERIES OF PANEL DISCUSSIONS WITH AUDIENCE PARTICIPATION

PRACTICAL ASPECTS OF MEDICAL TREATMENT OF VERTIGO

Brian McCabe, Iowa City, Iowa; Professor and Head of
Department of Otolaryngology and Maxillo Facial Surgery

Arthur W. Samuelson, Bridgeport

John H. Perkins, Hartford

Edward B. Gaynor, Norwalk

FRONTAL SINUS SURGERY

Brian McCabe, Iowa City, Iowa

John A. Kirschner, New Haven

John G. O'Hurley, Hartford

Seymour J. Baum, Fairfield

CANAL WALL—UP OR DOWN?

Brian McCabe, Iowa City, Iowa

Keat-Jin Lee, New Haven

Davis R. McKee, Stamford

Robert A. Gryboski, New Britain

SECTION ON DERMATOLOGY AND SYPHILOLOGY

11:00 A.M.

Wednesday, April 20, 1977

Stratford Motor Inn, Stratford, Connecticut

President: Brian J. McGrath, Guilford

Secretary: Gustave Sirot, New Haven

11:00 BUSINESS MEETING

12:30 LUNCHEON

1:30 ALL YOU EVER WANTED TO KNOW ABOUT IMMUNOLOGY

JOHN DWYER, NEW HAVEN, CONNECTICUT;

Associate Professor of Medicine and Pediatrics

SPECIAL NOTICES

THE CONNECTICUT STATE MEDICAL SOCIETY

acknowledges with thanks

convention program grants received from:

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TECHNICAL EXHIBITS

Aetna Life and Casualty, Hartford, Connecticut

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THE PRIMARY SURGICAL TREATMENT OF CARCINOMA OF THE BREAST

(continued from pg. 249)

for age difference, the correction made the two quite similar and any difference was not significant.

Homogeneous group

"When the group was analyzed according to the type of operation, the observed survival was nearly identical, both for node-negative and node-positive patients, irrespective of the type of mastectomy performed." For patients treated by modified mastectomy, observed survival was 84% when nodes were negative, and 66% when nodes were positive; in the standard radical mastectomy, survival was 86% with negative nodes, and 66% with positive nodes.

DISCUSSION

The results of this study did not demonstrate any significant difference in survival of patients treated by modified radical procedure compared with those treated by the classical radical mastectomy.

"The surgical trend at this Clinic is thus quite clear. Once the bastion for the classical radical mastectomy, we have now adopted the modified radical mastectomy as our treatment for primary breast cancer. The effectiveness of this trend is substantiated by the results here presented and we believe that this trend will continue."

Abstracted from a paper published in Mayo Clinic Proceedings, Vol. 51, No. 7, July 1976.

Letters To The Editor

HISTO-PATHOLOGIC EXAMINATION OF EXCISED LESIONS

To the Editor: When lesions are excised outside the hospital, the question frequently arises whether the specimen should be sent to the pathologist or not.

The Cancer Coordinating Committee of the Connecticut State Medical Society after extensive study, discussion and consultation has drawn up some guidelines concerning the advisability of histopathologic examination of excised lesions:

1. Most warts, benign keratoses, sebaceous and epidermal inclusion cysts need not be sent for histo-pathologic examination unless gross inspection arouses some suspicion.
2. All moles and nevi which are removed should be sent for histopathologic examination.
3. It is recommended that when practical moles, nevi and suspected melanomas be excised in toto rather than incised deeply for biopsy.

The Committee suggests that the use of these guidelines would be highly desirable.

E. Tremain Bradley, M.D.

Norwalk, CT.

*Chairman, Cancer Coordinating Committee
Connecticut State Medical Society*

FROM THE EXECUTIVE DIRECTOR'S OFFICE

160 St. Ronan Street, New Haven, Conn. 06511
Telephone 865-0587

Francis G. Sweeney
*Assistant Executive Director
Public Affairs*

William R. Richards, M.D.
Executive Director
Josephine P. Lindquist
Associate Executive Director

Robert J. Brunell
*Assistant Executive Director
Scientific Activities*

Summary of Actions Council Meeting Thursday, March 10, 1977

I. Attendance

Present in addition to the Chairman, Dr. D.A. Grendon, and the Vice Chairman, Dr. Guy W. Van Syckle, were: Drs. Spitz, Friedberg, Freedman, Backhus, Johnson, Hess, Canzonetti, Bradley, Cramer, Fabro, Kamens, Harkins, James, Mendillo, Krinsky, Sonnen, McGarry, Beck, Ahrens, Sadowski, Vidone and Eslami.

Also present: Mrs. Lindquist, Mrs. Arafeh (CSMS Auxiliary), Mr. Sweeney, Mr. Brunell and Dr. Richards.

Absent were: Drs. Nolan, Whalen, Magram, Parrella, Barrett, Zlotzky and Middleton.

II. Routine Business

Approval of Minutes

As published and distributed, it was VOTED to approve the minutes of the meeting on February 16, 1977, except that under the item titled "Nominee for Honorary Membership" (Page 5) it is to be noted that the nominee, Dr. George E. Palade, is a Nobel Laureate.

Life Memberships

It was VOTED to approve applications for Life Membership received from the following eligible Active Members:

Marcus E. Cox, St. Mary's Hospital, 56 Franklin Street, Waterbury

David Nagourney, 1756 East Main Street, Bridgeport

Date of Next Meeting

The Chairman set the date of the next Council meeting as Wednesday, April 6, 1977.

III. Old, New and Special Business

Reports on HSA Activities

It was VOTED to receive as information a series of verbal reports on Health Systems Agency activities by members of the Council who are serving with the five area Agencies. Those reporting were: Dr. Kamens (Area I); Dr. Hess (Area II); Dr. Krinsky (Area III); Dr. Friedberg (Area IV); and Dr. Fabro (Area V). Dr.

Friedberg also reported on his brief experience as chairman of the Statewide Health Coordinating Council (SHCC), the agency to which the area HSAs report and which will coordinate their activities. In brief, it appears that all five HSAs are organized and beginning to function; that some are farther ahead in development than others; that some are providing more opportunity for physician input than others; and that in at least one, the attitude of community physicians toward HSA is distinctly negative.

Progress Report on FTC Complaint and Related Developments

It was VOTED to receive as information a subject report presented verbally by the Executive Director and others. The developments reported on were: A further subpoena from the FTC for additional CSMS documents, dating back to 1955; a subpoena from the Federal Elections Commission demanding documents and information concerning the Society's relation to COMPAC; FTC subpoena served on the Hartford County Medical Association demanding bylaws, documents, correspondence, etc. relating to the "Principles of Ethics" and the administration thereof by HCMA; FTC subpoena served on COMPAC, demanding information, documents, etc. concerning COMPAC activities and the relationship of COMPAC (if any) to the Society and to other political action committees or medical organizations.

Report of CSMS Delegation to the AMA

It was VOTED to receive as information a subject report presented verbally by J. Alfred Fabro, AMA Delegate and several other members of the Connecticut Delegation. The principal matters reported on were:

- (a) That a report on the proceedings of the 1976 Interim Session of the AMA House of Delegates (Philadelphia) will be submitted to the CSMS House of Delegates in April.
- (b) That a resolution requesting CSMS endorsement of the AMA's new version of the former "Med-icredit" bill (HR 6222) will be submitted to the CSMS House of Delegates at the April meeting.

(c) That the Delegation proposed to introduce resolutions at the forthcoming meeting of the AMA House of Delegates in San Francisco on the following subjects. The concern of physicians about the effects of scientific developments in medicine on medical practice; The labelling of over-the-counter medications to identify the pharmaceutical ingredients contained therein; Hospital privileges for qualified family practitioners; The current and future relationships between physicians and nurses in the care of the patient; A definition of death; "Unnecessary Surgery"; Mechanisms for communicating with physicians, members and non-members, by the AMA; The practice of the Food and Drug Administration to withhold or delay approval of new drugs—especially those being used currently by physicians in foreign countries.

The Council further VOTED to approve, in concept, the introduction of resolutions to AMA which are based on the eight subjects listed in (c) above.

Report-Proposed Format for House of Delegates Meetings

It was VOTED to receive as information a subject report submitted by an Ad Hoc Committee appointed by the Council (12/15/76). It was further VOTED, with minor amendment, to approve the report and the recommendations contained therein. In brief, the report advocates that steps be taken to assure that members of the House are present on time, so that the Call to Order may be made at the scheduled hour; that resolutions and reports be handled expeditiously, by direct acceptance whenever possible, to the end that the "caseloads" of reference committees be kept to a minimum and the time of the House conserved; that the mid-day luncheon be devoid of speakers or other types of programs, to the end that convening for the afternoon session will not be delayed; and that the House complete action on its business agenda before proceeding with introduction of guests, presentations and awards, etc.

Resolution re Connecticut Tumor Registry

Being apprised that a recent opinion rendered by the State Attorney General's office indicated that a new law on "confidentiality" (P.A. 76-421) may prohibit the sharing of the Registry's statistical data with other agencies engaged in cancer research and control, which it has done for many years past, the Council VOTED to adopt the following resolution (introduced by the Cancer Coordinating Committee):

RESOLVED: That the Council of the Connecticut State Medical Society endorse the current practices and functions of the State Department of Health with respect to collection and transmission of in-

dividual identifying information that may be covered by Public Act 76-421; support their continuation under existing laws or under amendments that may be required to permit such continuation; and emphasize that both cancer research and cancer control in Connecticut, as particular health activities, require such continuation.

It was further VOTED to inform the Commissioner of Health of this action.

Further Report on Planned CME Workshop

It was VOTED to receive as information a memorandum submitted by Vincent A. DeLuca, chairman of the Committee on Continuing Medical Education, which asked the Council to reconsider its 2/16/77 action which directed the Committee to shelve its plans for a May 11 conference on "Planning CME in Community Hospitals" and, instead, to cooperate with the Area II PSRO in holding a CME function on May 18. Dr. DeLuca pointed out that the two functions were entirely different as to subject matter; that the CME Committee did not have expertise in the areas covered by the PSRO function; and that the two functions would have appeal for different types of audience. After considering the merits of Dr. DeLuca's comments, the Council VOTED to rescind its subject action of 2/16/77 and further VOTED to authorize the Committee on CME to proceed with its plans for a May 11 conference and to allocate funds in an amount of up to \$500 in support of such conference. Note was made that the Committee might be able to obtain supporting funds from other sources, in which case the Society's actual contribution might be reduced.

Communication re The Gaylord Hospital

It was VOTED to receive as information a communication from The Gaylord Hospital, signed by Philip B. Arnold, M.D., Chief of Rehabilitation Services, and Curtland C. Brown, Jr., M.D., Medical Director, which sought the assistance of the Society in resolving problems being encountered re Medicare payments for services rendered by the Hospital. In the opinion of Drs. Brown and Curtland, the problems stem from a "lack of understanding of the differences between rehabilitation medicine and acute care medicine" on the part of the Bureau of Health Insurance, rather than on the part of the Medicare intermediary, the Travelers Insurance Company. The effect of the problems is to equate Gaylord Hospital with a skilled nursing home (which is entirely in error) and to have Travelers directed by the BHI to process the institution's claims for payment on the basis of that unwarranted equation. After considering the subject communication, and receiving contributory information from several members, the Council VOTED that

the Council go on record as re-emphasizing that care should be given at the most effective level, taking into account the quality and costs of such care, and to suggest to the Gaylord Hospital administration and/or medical staff that an appeal be made to the Area II-PSRO to act as an interface between the Bureau of Health Insurance and the intermediary (Travelers) in an effort to resolve the existing problems; further, that if Area II-PSRO is unable to resolve the problems, the matter be referred to the Statewide Professional Standards Review Council.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on March 10, 1977. Detailed minutes of the meeting are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

NOTICES

ST. FRANCIS HOSPITAL
May 18, 1977

The Immunology Division of the Department of Laboratories is pleased to announce the following lecture as a part of the continuing series of lectures on "The Current Concept and Trend in Clinical Immunology".

May 18, 1977, *Kidney Transplantation-1977*, H.M. Lee, M.D., Profession of Surgery, Chairman of Division of Vascular Surgery and Director of Clinical Transplant Center, Medical College of Virginia.

TIME: 11:00 a.m.—12:00 Noon
PLACE: Amphitheater, ST. FRANCIS HOSPITAL,
114 Woodland Street, Hartford, CT

FOR INFORMATION:
Jayson Hyun, M.D.
Director of Immunology Laboratory
Tel. (203) 548-4368

YALE DEPARTMENT OF DERMATOLOGY

The Department of Dermatology at Yale is initiating a consulting service for diagnosis and treatment of pigmentary disorders at the Yale-New Haven Hospital. We are interested in evaluating patients with any pigmentary disorders whatsoever including nevi, malanomas, melasma, loss of pigment, vitiligo, poliosis, albinism, etc. In conjunction with this new service, Dr. Aaron B. Lerner and Dr. James J. Nordlund will be writing several articles for *Connecticut Medicine* to inform the medical community of current state of the knowledge about pigmentary disorders. For information or appointments, please call 436-4481.



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In Memoriam

Martin, Raymond A., University of Vermont, 1937. Dr. Martin was a urologist in the Fairfield area since 1941 and was the founder of the Urological Associates of Bridgeport. He was also an Army veteran of World War II, serving as captain in the medical corps. He served as a surgeon and urologist in the European theater of operations and also served in the Pacific theater. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Martin died February 2, 1977, at the age of 64.

Milstone, Jacob H., Johns Hopkins, 1937. Dr. Milstone was a pathologist in the New Haven area since 1951. He served in the U.S. Army as a Major from 1942-1946. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Milstone died January 27, 1977, at the age of 64.

Otis, Israel S., George Washington Medical School, 1917. Dr. Otis retired from the practice of medicine and surgery in 1966. He had served Meriden as city physician and as a member and president of the city Board of Education, 1932 to 1936. His career in Meriden included being attending surgeon for many years at Meriden Hospital; former chief of surgical services at the hospital; surgical consultant at Bradley Memorial Hospital in Southington, and on the courtesy staff at the World War II Veterans' Memorial Hospital. He was a member of the New Haven County Medical Association and the Connecticut State Medical Society. Dr. Otis died January 30, 1977, at the age of 82.

Partridge, Winthrop P., Harvard Medical School, 1920. Dr. Winthrop was a pediatrician in the Hartford area since 1922, until his retirement in 1972. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society. Dr. Partridge died May 29, 1976, at the age of 82.

Riendeau, Pauline, University of Paris, 1927. Dr. Riendeau was a general practitioner in the Litchfield area since 1933. She served at Norwich Hospital and later established a practice of medicine in Torrington until her retirement in 1966. Dr. Riendeau died January 20, 1977, at the age of 81.

Robinson, David, Johns Hopkins, 1942. Dr. Robinson was a obstetrician-gynecologist in the Hartford area since 1946. He served during World War II as a captain in the Army Medical Corps and was an infantry battalion surgeon in the European Theater. He received the Bronze Star and the Purple Heart decorations. He was former chief of obstetrics and gynecology at Mt. Sinai Hospital and a clinical associate in gynecology at the University of Connecticut Health Center in Farmington. Dr. Robinson was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; he also served as a member of the Council of the Connecticut State Medical Society. Dr. Robinson died January 22, 1977, at the age of 59.

Stevens, John S., University of Maryland, 1941. Dr. Stevens served as a Commander in the Medical Corps of the U.S. Navy in World War II. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Stevens died February 25, 1977, at the age of 62.

Warring, Howard, Howard University College of Medicine, 1928. Dr. Warring was a general practitioner in the Hartford area since 1929. He practiced medicine in Hartford 47 years and was a school physician for the City of Hartford 33 years. He was a member of the courtesy staffs of St. Francis Hospital and Medical Center and Mt. Sinai Hospital, and Medical examiner for the Town of Bloomfield 15 years. Dr. Warring died January 29, 1977, at the age of 74.

Weiner, Julius G., Yale Medical School, 1929. Dr. Weiner was chief of obstetrics and gynecology at Mt. Sinai Hospital in Hartford, until his retirement in 1971. He was a member of the Hartford County Medical Society and the Connecticut State Medical Society. Dr. Weiner died February 18, 1977, at the age of 73.

Wight, Winfield E., Bowdoin Medical School, 1920. Dr. Wight was a general practitioner and surgeon in the Litchfield area since 1920. He opened his practice in Thomaston in 1922 and remained active in it until his retirement almost exactly one year ago. He was a member of the Litchfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Wight died February 2, 1977, at the age of 81.

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiry of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511, (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine*.

PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

Anesthesia: 33 years of age with Connecticut license wishes group practice in a medium sized community. Eligible. National Boards. Residency at Yale-New Haven Hospital. Available July 1977. J. John Barbieri, M.D., 123 York St., 22L, New Haven, CT. 06511

Family Practice: Available July 1977. Connecticut license. Passed National Boards. Wishes group or solo practice in a small community. Eligible on completion of residency at Middlesex Memorial Hospital in July. 26 years of age. Arnold Berman, M.D., 77 Crescent St., Middletown, CT 06457.

Family Practice or Emergency Room: Full-time. Presently in practice. Solo practice in large community. Connecticut license. Available now. Abul B.A. Kareem, M.D., 975 Newfield Ave., Stamford, CT 06905.

Family Practice: Chief resident and instructor at Hershey Medical Center, PA, M.D. from Vermont. Passed National Boards. Wishes group, associate practice in medium or small community. Available July 1977. 31 years of age. Stephen T. O'Brien, M.D., 248 University Manor, Hershey, PA 17033.

Family Practice: 29 years of age. Available August 1977. National Boards. Prefers 4-5 person F.P. group in a medium sized community. M.D. from Boston University. Stanley E. Yellin, M.D., 2105 Wrenn St., Greensboro, NC 27408.

Family Practice: Connecticut license. Available Sept. '77. Prefers taking over established practice if one is available. Board Eligible. Medium sized community. Presently in practice. Joseph M. Kaplan, M.D., 2501 Avenue D, Brooklyn, NY 11226.

Internal Medicine: Board eligible. Available July 1977. Prefers medium or small sized community. Will consider ER work.. M.D. from the University of the East in the Philippines. FLEX. Completing training at Kingsbrook Jewish Medical Center, Brooklyn, New York. Silvestre H. Almirol, Jr., M.D., 100 East 92nd Street, Apt. 3K, Brooklyn, NY 11212.

Internal Medicine: Available June 1977. Group practice. Board eligible. M.D. and training from University of Iowa, 30 years old. Charles W. Graeber, M.D., 2929 Radcliffe, Iowa City, IA 52240.

Internal Medicine: Available July 1977. Board eligible. Desires medium or small sized community in a small group setting. Dartmouth graduate. M.D. from Downstate Medical School. Internship and residency in Buffalo. 29 years old. Married. Mark C. Hamilton, M.D., 149 Creekside Drive, Tonawanda, NY 14150.

Internal Medicine: Board eligible. FLEX. Available July 1977. Completing training at Queens Hospital Center, Jamaica, NY. A.N.

Internal Medicine: Board eligible. Available July 1977. Completing training at Wilmington Medical Center. D.O. from Philadelphia College of Osteopathic Medicine, 28 years old. Married. Desires large community in solo, group or associate practice. Harvey T. Starr, D.O., Colony North Apts. 2 Colony Blvd., #139, Wilmington, DE 19802.

Internal Medicine: Board eligible. Available July 1977. M.D. from University of Virginia, Postgraduate training at Nassau County Medical Center. Desires group practice. Joseph I. Verdirame, M.D., 200 Carman Avenue, Apt. 6G, East Meadow, NY 11554.

Internal Medicine: Primary Care with some teaching. Available September 1977. Board eligible. Completing special training at University of Rochester. 33 years old. M.D. from Jefferson Medical College. Solo, group or associate practice. Edward B. Yellig, M.D., 341 Mulberry Street, Rochester, NY 14620.

Internal Medicine: Primary Care. Desires university affiliated community hospital. Special interest in Fairfield County. Available July 1977. Board eligible. M.D. from Medical College of Virginia. Completing residency at Norwalk Hospital. Victor J. Tricarico, M.D., 23 Woodbury Avenue, Norwalk, CT 06850.

Internal Medicine (Cardiology): Group or associate practice. Board certified. 32 years old. Married. Presently instructor at the University of Rochester. John S. Zesk, M.D., University of Rochester School of Medicine, P.O. Box 679, Rochester, NY 14642.

Internal Medicine (Cardiology): Board certified. Solo or associate. Completing fellowship at Beth Israel in NYC. S.H. Nanavati, M.D., 353 E. 17th Street, #9B, New York, NY 10003.

Internal Medicine (Cardiology): Available July 1977. Completing fellowship at Duke Medical Center. M.D. and training at University of Pennsylvania. 32 years old. Board certified in IM. Board eligible in cardiology. Burton Silverstein, M.D., 504 Sharon Road, Chapel Hill, NC 27514.

Internal Medicine (Cardiology): Special interest in echocardiography, both in performing and interpreting echocardiograms. M.D. and all training at Cornell-New York University. Senior residency at University of Michigan. Fellowship at Strong Memorial Hospital. Board certified in 1975. Karl C. Sze, M.D., 252-C Quinby Road, Rochester, New York 14623.

Internal Medicine (Cardiology): Group practice. Trained in invasive and non-invasive cardiovascular techniques. M.D. from University of California. All post graduate training at University of Iowa, Board certified. Available July 1977. M.A. Thompson, Jr., M.D., 1417 Derwin, Iowa City, IA 52240.

Internal Medicine (Cardiology): Board certified. Group, associate or institutional practice. Chief medical resident at Memorial Hospital, Brown University. Fellowship at Wayne State, Available July 1977. D.R. Vemireddy, M.D., 9339 Pickwick Circle West, Taylor, MI 48180.

Internal Medicine (Gastroenterology): Board certified ABIM, M.D. from NYU. Internship and residency at Boston University Hospital. Fellowship at New Jersey College of Medicine. Available July 1977. 30 years old. Married. Solo, group or associate practice. Resume on file at CSMS. SW-GI.

Internal Medicine (Gastroenterology): Board certified. FLEX. Completing Hutzel Hospital, Detroit, Michigan. Available July 1977. S.K. Singal, M.D., 3737 Beaubien #909, Detroit, MI 48201.

Internal Medicine (Gastroenterology): Board certified. Group or associate practice desired. M.D. from Cornell. Internship and residency at N.Y.-Cornell Fellowship at University of Pennsylvania. Mark A. Sullivan, M.D., 2834 Midvalle Ave., Philadelphia, PA 19129.

Internal Medicine (Gastroenterology): Prefers multispecialty group. Board certified. 30 years old. Married. M.D. from Upstate Medical School, NY. Completing fellowship at North Carolina Memorial Hospital. Internship and residency at University of Virginia. Keith S. Turner, M.D., 416 Hickory Drive, Chapel Hill, NC 27514.

Internal Medicine (Gastroenterology): Board certified ABIM. Available August 1977. Fellowship at Brooke Army Hospital, San Antonio, TX. Presently on active. 32 years old. Married. M.D. from New Jersey College of Medicine. Interned at St. Vincent Hospital, Worcester, MA. James L. Stammer, M.D., 5314 LaCienega Circle, San Antonio, TX 78233.

Internal Medicine (Hematology-Oncology): FLEX. Board eligible. Completing training at Long Island Jewish Hospital. 32 years old. Available July 1977. C.U. Zachariah, M.D., 164-10 84th Avenue, Apt. 4G, Queens, NY 11432.

Internal Medicine (Nephrology): Board certified in IM. Completing fellowship from Albany and Thomas Jefferson Hospitals. M.D. from University of Cincinnati. Interned at NY Medical College. Charles F. Schiffer, M.D., 4 Grant Court, Guilderland, NY 12084.

Internal Medicine (Pulmonary): Board certified. Available summer of 1977. Completing fellowship at Bellevue Hospital. M.D. from Boston University. Prefers group or associate practice. 31 years old. Resume on file at CSMS. J.R.S.-Pulmonary.

OB/GYN: Connecticut license. 37 years of age. Eligible June 1977. Group, solo or associate practice. Residency at St. Vincent's Hospital, Bridgeport. Contact CSMS-Ob/Gyn-MB.

OB/GYN: 30 years of age. FLEX. Eligible. Group or associate type practice. Internship and residency Connecticut Health Center and New Britain General. Available July 1977. Bernhard Berger, M.D., 33 Highland St., New Britain, CT 06052.

OB/GYN: Available July 1977. 32 years of age. FLEX. Board eligible. Solo, group or associate practice. Internship at St. Mary's Hospital, Waterbury. Residency Brooklyn-Cumberland Medical Center and Boston City Hospital. James Yuan Long Ger, M.D., 860 Harrison Avenue, Box 21, Boston, MA 02118.

OB/GYN: Eligible July 1977. Internship and residency 1972-1973 at Norwalk Hospital. Presently doing residency program at Montefiore Hospital. 36 years of age. Group or associate practice. Seung N. Kim, M.D., 3411 Wayne Ave., 8-L, Bronx, NY 10467.

OB/GYN: Connecticut license. 32 years of age. National Boards, eligible. Solo, group, associate or institutional practice. M.D. from New York Medical College. Internship and residency Kings County Hospital-Downstate, New York. Available July 1977. William L. Schneiderman, M.D., 1655 Flatbush Avenue, Apt. A-1503, Brooklyn, NY 11210.

OB/GYN: Available July 1977. National Boards, eligible. Solo practice. Internship at Long Island College Hospital. Residency Bridgeport Hospital. Chaw P. Sun, M.D., 71 Ford Place, Bridgeport, CT 06610.

Ophthalmology: FLEX. Would like to join an associate or multi-speciality group in a medium sized town. 35 years of age. Available July 1977. Appireddy Bommareddy, M.D., 9293 Pickwick East, Taylor, MI 48180.

Ophthalmology: Interested in areas closer to New York, will consider all areas. Solo, group or buying a practice. 30 years of age. National Boards. Eligible. Available July 1977. Theodore M. Ingis, M.D., 430 E. 63rd St., Apt. 3-L, New York, NY 10021.

Ophthalmology: Available July 1977. 31 years of age. Certified, National Boards. Presently in practice. Group or associate practice in medium sized community. M.D. from University of Rochester. Gary S. Clorfeine, M.D., 541-B Winans Road, West Point, NY 10996.

Ophthalmology: 31 years of age. Connecticut license. Presently in practice wishes solo or associate practice in Connecticut. National Boards. Eligible. M.D. from State University of New York. Available July 1977. Sigmund S. Gould, M.D., 4132 Wyndybrow Drive, Portsmouth, VA 23703.

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(If no name is listed, contact the Physician Placement Service for more details.)

Emergency Medicine: Contact Melvin D. Orlins., M.D., Norwalk Hospital, Norwalk, Ct. 06856. 203-838-3611, Ext. 596.

Family Practice: Contact Andrew F. Turano, M.D., Search Committee for Colchester area, 80 South Main Street, Middletown, CT 06457.

Family Practice: Long established practice of solo physician about to retire, available in New Haven. Contact CSMS.

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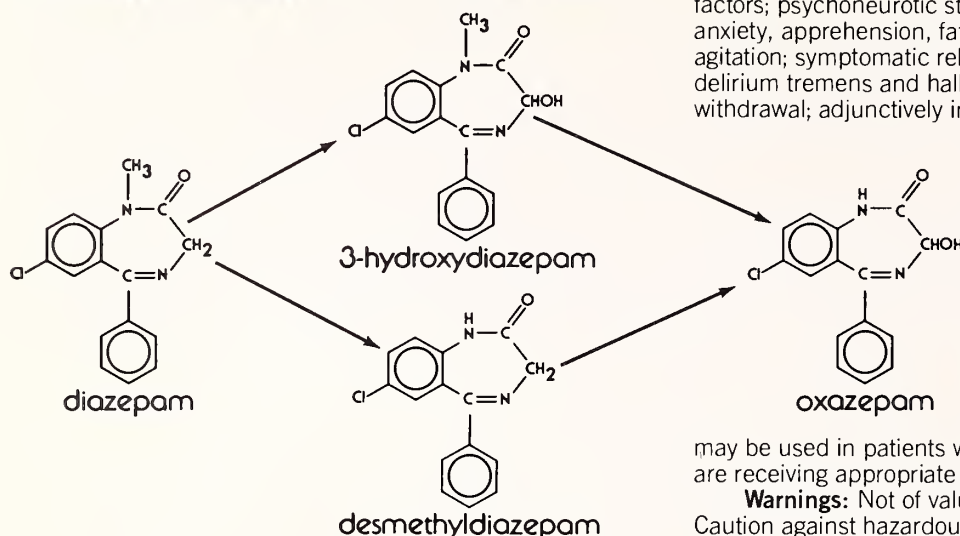
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Adjuvant Treatment of Cancer

I. Large Bowel Cancer

(This is the first of a series of articles on the adjuvant treatment of solid tumors)

J. Scott Nystrom, M.D. and Michael V. Viola, M.D.

ABSTRACT—Surgery remains the most effective treatment modality for patients with large bowel cancer. However, innovative surgical techniques have not improved survival rates for colorectal cancer in twenty-five years.

Attempts at increasing survival with chemotherapy as an adjunct to surgery remains inconclusive and controversial. Many adjuvant chemotherapy trials have failed to recognize those prognostic factors, viz., nodal involvement, serosal penetration, vascular or perineural invasion, and microscopic invasion at margins of resection, which characterize certain patients at high risk for recurrent cancer. Failure to include only high risk patients in adjuvant chemotherapy trials are, in part, responsible for the lackluster performance to date.

For rectal cancer preoperative irradiation increases surgical curability by reduction of pathologic staging, but it has not increased survival in patients with persistent nodal involvement.

Immunotherapy is a potentially exciting treatment modality but clinically untested. An adjuvant immunotherapy protocol for high risk patients is described.

Introduction

Curative therapy for invasive adenocarcinoma of the large bowel continues to be radical surgical excision. Early attempts to prolong survival by employing radiation and chemotherapy, either as pre-operative or as post-surgical adjuvants, have not been successful. It is now believed adjuvant therapies may be effective in subgroups of patients who demonstrate the presence of certain risk factors which are related to disease recurrence. If so, the role of immunomanipulation also is promising. This paper summarizes previous approaches for early treatment of large bowel cancer in order to crystallize the rationale for adjuvant therapy including immunomanipulation.

Radiation Therapy in Rectal Cancer

Radiation therapy for patients with unresectable primary large bowel cancer or local recurrence of malignancy has been shown to have significant pallia-

tive effects.¹ Accordingly, it has been postulated that pre-operative irradiation to rectal and low sigmoid cancers would improve survival.² A retrospective survival study of 1700 previously untreated patients with rectal cancer has been reported from Memorial Hospital. Pre-operative radiation therapy (2000 rads in two weeks) demonstrated a significant increase in five year survival (37%) over surgery alone (23%) in patients with lymph node involvement.³ However, a partially randomized prospective study was subsequently initiated which revealed the opposite findings with surgery alone having slightly increased proportion of patients surviving 5 years when compared to survival in those patients receiving both radiation therapy and surgery.⁴

Several reviews of the Veterans Administration Surgical Adjuvant Group's (VASAG) pre-operative radiation protocol for rectal cancer have revealed a slight increase in survival in patients receiving radiation therapy (2000-2500 rads in two weeks) plus abdominoperineal resection. Concurrent randomized controls receiving surgery alone were used in these studies.^{5,6} The current VASAG pre-operative radiation therapy protocol utilizes 3150 rads in 18 fractions randomly matched against no pre-operative treatment.

The Central Oncology Group (COG) and the Radiation Therapy Oncology Group have attempted to conduct a study (COG #7240) comparing high (4000-4600 rads in 4-5 weeks) and low dose (2000-2500 rads in 2 weeks) pre-operative radiation therapy in rectal cancer. Both groups of patients will be compared to a no pre-operative treatment group. No data is available from this study.

The European Organization for Research on Treatment of Cancer uses 3450 rads pre-operatively over an 18 day period for rectal cancer. A comparison is being made to pre-operative irradiation plus 5-FU chemotherapy.⁶

The above-cited studies permit certain conclusions concerning pre-operative radiation therapy in rectal cancer: (a) Pre-operative rectal irradiation reduces the frequency of lymph node involvement.^{5,6} By reducing pathologic stage, radiation therapy appears to increase surgical curability (without increasing surgical morbidity) even when low dose irradiation is employed; (b) Pre-operative rectal irradiation reduces local recurrence, regardless of pathologic staging⁶; (c)

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However, no randomized study has yet shown a significant survival benefit with pre-operative radiation in patients who continue to demonstrate nodal involvement at the time of surgery.

Factors Associated With Poor Prognosis in Large Bowel Cancer

One of the pitfalls that plagued earlier surgical adjuvant chemotherapy trials was the unawareness of patient characteristics associated with a high probability of disease recurrence, regardless of the adequacy of the surgical resection. These include:

1. Pathologic stage of the tumor has been shown to be a major prognostic factor according to Dukes:⁷
 - A—Cases in which the tumor has not penetrated the muscle wall of the bowel;
 - B—Cases in which tumor extends to the pericolic or perirectal tissues but has not reached the lymph nodes;
 - C—Cases in which tumor has metastasized to the proximal (C₁) or regional (C₂) lymph nodes; and
 - D—Cases in which tumor has metastasized to distant locations.

Utilizing this classification survival at 5 years was:²⁶ Dukes' A—60% to 80%, Dukes' B—25% to 65%, Dukes' C—6% to 28%, Dukes' D involving liver or lung—less than 15%.⁸

2. Presence of gross or microscopic blood vessel invasion in the resected primary specimen has been associated with 19% to 37% 5 year survival.^{9,10,11} In patients with vascular invasion, the probability of recurrent tumor is 74%.¹²
3. Perineural involvement in the resected surgical specimen has been related to a 20% 5 year patient survival.¹¹
4. Any combination of lymph node, vascular or perineural tumor infiltration has additive effects in terms of decreasing the chances of a 5 year survival.¹¹
5. An exceedingly high rate of anastomotic recurrence is observed in patients whose resection margins are not free of microscopic tumor foci.

In one review, first disease recurrence within 18 months of surgery was observed in more than 75% of patients who exhibited one of the above poor prognostic factors.¹³

Adjuvant Chemotherapy

Adjuvant chemotherapy was initially used in an attempt to destroy cancerous cells left in the operative field and to prevent spread via the blood stream or lymphatics during surgery. Therefore, early studies employed short duration adjuvant therapy to irradi-

cate the small pool of locally residual cancer cells. At first, local irrigation of the bowel ends with half-strength Dakin's solution or 1:500 perchloride of Mercury was advocated.^{14,15} Later, systematic chemotherapy began with early randomized controlled studies testing effects of triethylene thiophosphoramide (Thio-tepa) and fluorodeoxyuridine (FUDR). Various routes of administration were used (intraperitoneal, mesenteric vein, intravenous) but were unsuccessful.^{16,17}

When intraluminal 5-Fluorouracil (5-FU) plus two days post-operative systemic 5-FU was used, increased survival in patients with lymph node involvement was demonstrated when compared to a retrospective no-treatment control group¹⁸. These observations have motivated the initiation of a randomized cooperative clinical study comparing intraluminal 5-FU in combination with systemic 5-FU after surgery to surgery alone.¹⁹

In 1971 the VASAG reported on a randomized study of no treatment compared with 5-FU treated colon cancer patients²⁰. 5-FU was given in the immediate post-operative period (14 days post-resection) for 5 successive days at 12 mg/kg body weight intravenously. Treatment assignment was not stratified by Dukes' classification or any other prognostic variables influencing disease recurrence, but only by the surgeon's opinion regarding potential curability. All patients were followed for duration of survival. Those patients who received surgical procedures termed "clinically palliative" and "clinically cured" received a second course of 5-FU six weeks later. There was no statistically significant difference with regards to 5 year survival or disease-free interval between treated and untreated populations in any of the patient groups. Furthermore, retrospective analysis by Dukes' classification again failed to demonstrate 5-FU superiority with respect to survival over control population. The 5 year survival rate for 308 patients undergoing "curative resection" demonstrated a 58.5% survival for treated 142 patients versus 49.4% survival for 166 control patients. The trend of this study appears to favor 5-FU treatment, but statistical significance is lacking.²¹ Thus, early trials utilizing Thio-tepa, FUDR and 5-FU have failed to demonstrate significant prolongation in survival. Doses, schedules, route of administration, the short duration of adjuvant treatment and disregard for prognostic factors in treatment assignment may be important factors in this failure.

The advocacy of prolonged intermittent systemic adjuvant chemotherapy came about with the realization that: (a) occult metastatic cancer sites can exist at the time of surgery and do not result exclusively from surgical manipulation; and (b) repeated courses of

treatment are necessary to irradiate this small residual tumor cell burden.

Prolonged intermittent 5-FU adjuvant therapy is being tested in a randomized prospective study by the COG.²² Prior to randomization to adjuvant 5-FU or to no treatment, patients with poor prognosis are classified as "curative" or "palliative" resection. Poor prognosis in the curative group includes the following factors:

1. Positive lymph nodes.
2. Serosal penetration or invasion of perirectal fat.
3. Blood vessel invasion.
4. Lymphatic invasion.
5. Cancer in other organs removed as part of the resection.

In this study, 5-FU was given intravenously at 12 mg/kg/day for 4 days and then 6 mg/kg/q.o.d. for 5 doses or to toxicity. Following this induction course, 5-FU was given weekly at 12 mg/kg for one year. Endpoints were first disease recurrence and death.

The follow-up period is still relatively short but at last report 49/64 (77%) of patients classified as "curative" resection were disease-free after treatment with 5-FU as compared to 42/63 (67%) of the patients similarly classified and assigned to no treatment.²² For both curative and palliative resected patients 5-FU treatment has not shown significant superiority over no treatment with respect to disease-free interval or five year survival.

The VASAG has also investigated prolonged intermittent chemotherapy (5-FU) in colon cancer. Chemotherapy was given in the same manner as in their prior study²⁰ but was repeated every 6 weeks for 18 months. Case accrual terminated in August 1973. To date, no difference has been demonstrated in patient survival associated with prolonged 5-FU treatment.

Lawrence has recently reported no significant treatment benefit, regardless of stage, with 5-FU used as a prolonged intermittent post-operative (one year) adjuvant in colorectal cancer patients. Treatment benefit was measured in terms of disease-free interval and survival²³.

Other non-randomized reports showing significant superiority of 5-FU over no treatment groups continue to plague the literature.²⁴ The question of 5-FU success in prolonging patient survival will not be answered by retrospective comparison to control populations.

The recent reports of higher than anticipated regression proportions in metastatic colon cancer when drugs with low individual activity are combined have prompted these drug combinations to be considered as adjuncts to surgery.^{25, 26} The use of combination chemotherapy as adjuncts to surgery adds further risk of systemic toxicity, difficult patient management,

interference with patient quality of life, and potentially greater immune "paralysis" (tolerance) to residual tumor burden. In spite of these potential difficulties, several cooperative groups have initiated studies using combination chemotherapy (viz., Me-CCNU plus 5-FU) as an adjunct to surgery.

Immunotherapy as Adjuvant Treatment

The effective clinical use of immunomanipulation may be manifest only at the time of minimal tumor burden, because host immune "paralysis" increases with increasing tumor burden.²⁷ Reactive regional lymph node hyperplasia with germinal center proliferation draining a primary malignancy has been observed in both breast and colon cancer.^{28, 29} This suggests a host immune response to the tumor. Post-operative irradiation of regional draining lymph nodes in breast cancer has been a common practice and now has been associated with decreased survival when compared to non-irradiated post-operative controls.³⁰ This disturbing observation perhaps reflects the result of lymph node destruction secondary to radiation therapy, thus "paralyzing" an important defense against dissemination.

Implementation of "non-specific" immunotherapy at the time of minimal tumor burden will theoretically stimulate cell-mediated immunity (CMI) and increase the intensity of low level antitumor immune responses leading to tumor rejection. The cells involved in this CMI anti-cancer effect include macrophages, lymphocytes, polymorphonuclear white cells, and to some extent, plasma cells. Some or all of these cell types may be stimulated by various immunotherapies. The degree of cellular response often depends on route of drug administration. In animal tumor systems the immunostimulants, *C. parvum* or BCG appear to have greater immunocytotoxicity to a cancer inoculum when given I.V. or I.P. as compared to S.C. administration.³¹ It is postulated from animal data that the intravenous route is superior to the subcutaneous route because of direct visceral systemic stimulation by intravenous delivery rather than the regional lymph node hyperplasia which follows subcutaneous administration.

A randomized surgical adjuvant protocol for colorectal cancer patients who have had "curative" surgical resections and who demonstrate any one of the poor prognostic factors listed above has been designed by the Western Cancer Study Group (WCSG) and the University of Connecticut Health Center (UCHC). The agents employed are immunostimulants: *Corynebacterium parvum* and Levamisole. *C. parvum* was chosen as an immunoadjuvant for several reasons: (a) It appears to be a potent anticancer immunostimulant in many animal tumors and even

more effective than BCG in identical immunoadjuvant animal tumor systems,³¹ (b) *C. parvum* is formalin-fixed and not capable of transmitting active disease, as is BCG, nor is it dependent on viable organisms for its immunostimulant properties as is BCG; (c) *C. parvum* is not plagued with variation in organism viability when obtained from different sources as is BCG; (d) *C. parvum* preparations do not demonstrate inconsistent dosage administration caused by cellular clumping within multidose vials as has been the case with BCG;³² (e) in Phase II clinical trials, *C. parvum* has shown single agent antitumor effect in several metastatic tumor types.³¹

C. parvum toxicity has been established in Phase I trials. Side effects include pain at injection site, fever, malaise, flu-like syndrome and sensitivity to barbiturates when given subcutaneously. In addition, severe chills, fever hypo- and hypertension may be observed when the agent is administered intravenously.³¹ Pain at subcutaneous injection sites can be obviated by mixing with xylocaine. Side effects tend to be more severe when *C. parvum* is given intravenously compared to subcutaneous injection.^{31,33} The high fevers and chills are associated with large intravenous doses and are most severe with the first intravenous injection, diminishing with subsequent doses. If initial intravenous doses are kept small and subsequent doses are slowly increased, these toxic effects may diminish.^{31,33}

Levamisole, an established antihelminthic, was discovered by Renoux and Renoux to possess immunostimulating properties in animals.³¹ Since their initial work, animal data has been accumulated to confirm and extend these observations. In human studies Levamisole has been found to restore recall skin test antigens, and to increase *in vitro* lymphocyte reactivity.³¹ In general, it appears that Levamisole increases a low level of pre-existing immunity rather than stimulating an immune response *de novo*. The mechanism by which this occurs may be macrophage stimulation via a serum factor (which is not the drug) found in Levamisole-treated patients.³⁴ Although its performance as an antitumor agent in animal models appears to be less than *C. parvum* or BCG, recent adjuvant studies by Rojas utilizing Levamisole in breast cancer patients and Amery in lung cancer patients have demonstrated increased disease-free intervals in these patients when compared to a randomized prospective treatment control group.^{35,36} Such preliminary reports are exciting but remain to be clinically confirmed. When given as discontinuous therapy, i.e., 3 days P.O. every 2 weeks, side effects occur in about 5% of patients. They include (a) CNS stimulation manifested by nervousness and insomnia; (b) gastrointestinal complaints, e.g., nausea and

vomiting (c) skin rash. There has been no adverse effect on liver, kidneys, or cardiac function recorded. Transient granulocytopenia has been observed in patients on long term continuous therapy.

Further discussion of current information on other promising non-specific immunostimulants such as BCG and methanol-extracted residue of BCG (MER) is beyond the scope of this article. Clinical trials of specific immunotherapy, e.g., transfer factor, immune RNA, modified tumor antigens, cell wall extracts, etc., are chiefly limited to single institution study in small numbers of patients because of the large procurement and logistic problems.

Proposed Cooperative Trials of Immunotherapy Adjuvant for Resected Colon Cancer

Several cooperative group studies which will use both chemotherapy and immunotherapy in combination are presently undergoing development, activation, and preliminary analysis. The Large Bowel Cancer Working Group has a protocol proposal prepared by Holyoke at Roswell Park Memorial Institute for "curative" post-surgical patients with adenocarcinoma of the colon. In this study there is randomization to 4 treatment arms: (a) control; (b) 5-FU + Me-CCNU; (c) MER alone; (d) 5-FU plus Me-CCNU and MER. The VASAG has amended their current colon adjuvant protocol #27 for patients with histologically proven residual disease. These patients will be randomized to prolonged intermittent chemotherapy (5-FU plus Me-CCNU) with or without MER. Further details concerning these proposals are not available. Preliminary results from M.D. Anderson Institute have reported increased disease-free interval using BCG with or without 5-FU as an adjunct to Dukes' C colon carcinoma.³⁷ Unfortunately their use of historical controls detracts from the importance of their data.

The WCSG and UCHC have elected not to combine chemotherapy and immunotherapy in a surgical adjuvant study for colon cancer. This is based on several reasons: (a) there are no conclusive data that single or combination adjuvant chemotherapy prolongs disease-free interval or survival for large bowel cancer; (b) chemotherapy may entail additional systemic toxicity and potential for impairment of quality of life; (3) while chemotherapy may enhance host immunoreactivity to large volume malignancies, it also may "paralyze" established nodal defense systems against minimal tumor cell numbers; (d) combination chemotherapy when used in an adjuvant setting leaves few alternative chemotherapeutic drugs available at first disease recurrence; (e) chemotherapy could potentially be antagonistic to immunomanipulation; (f) information about dose, routes, and single-

agent effectiveness for immunostimulants should be established prior to combination with chemotherapeutic regimens.

The WCSG-UCHC study employs immunotherapy only for adjuvant treatment of patients with totally resected colorectal carcinoma and poor prognostic indicators. The patients will be randomized to: (a) placebo; (b) Levamisole; (c) *C. parvum* S.C.; (d) *C. parvum* I.V. Disease-free interval, survival and side effects will be the endpoints of treatment effectiveness.

As in any large scale study assessing the effectiveness of adjuvant therapy, case accrual is a critical aspect. A study designed for long term follow-up must encourage rapid case accrual. The UCHC invites any interested physicians seeking further information concerning this study and possible case referral to contact the authors. Participating UCHC investigators are very willing to assist physicians in their area who have potential patients to enroll.

Summary

An historical review of early treatment of large bowel cancer is presented. Several observations concerning the efficacy of single modality therapy can be made with regards to improving survival. (a) Since newer surgical techniques have not altered survival rates in 25 years, it appears that further surgical manipulation is unlikely to demonstrate future survival benefit; (b) Preoperative radiation therapy for rectal cancer both improves surgical curability by reducing pathological state and reduces local recurrence; but it has not demonstrated increased survival in patients with persistent nodal disease; (c) Short term adjuvant chemotherapy is of no apparent value in increasing survival; prolonged intermittent adjuvant chemotherapy has not yet demonstrated increased survival. The use of combination chemotherapy as an adjunct to surgery is currently being evaluated and no data as to its efficacy are available; (d) The employment of immunotherapy as an adjunct to surgery is theoretically sound and preliminary studies are very promising.³⁷ Immunotherapy as proposed by the WCSG-UCHC is described. If immunotherapy, chemotherapy, or radiation therapy are proven to be effective in increasing survival in large bowel cancer, then ultimately a multimodality approach may be adapted to further influence disease curability.

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Cardiac Rehabilitation: The New Britain Program

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Introduction

Patients with ischemic heart disease comprise a population restricted by symptoms and by medical caution, but remain very much at risk from the same correctible factors which contributed to their illness. 57% of our patients with myocardial infarction are smokers, 40% hypertensive and 20% hypercholesterolemic. Many exhibit so-called coronary-prone behavior patterns. A large proportion leave the hospital with incompletely controlled arrhythmias. The New Britain General Hospital—New Britain Y.M.C.A. Cardiac Rehabilitation Program was begun in 1971 in an effort to control coronary risk factors, achieve physical and psychological conditioning, and return participants to the fullest activity consistent with their individually-measured levels of cardiovascular function. It achieves these ends by mobilizing a variety of health services available in the community, hospital and Y.M.C.A. In this communication, we describe our methods, evolved over 4½ years in the treatment of 496 patients. We will report the results of their cardiovascular conditioning in a subsequent paper.

Background

Hypertension, cigarette smoking and blood lipid abnormalities are well-established coronary risk factors, and are worthwhile targets for a preventive community program.¹ Many now recognize the importance of efforts to alter abnormal behavioral

patterns and affective states whether these precede or derive from symptomatic ischemic heart disease.² To be truly effective, efforts at rehabilitation of the cardiac patient must encompass all of these goals in a holistic approach to the patient.

The role of physical exercise in prevention and therapy of ischemic heart disease remains incompletely defined. Numerous investigators have attempted to correlate exercise habits with the incidence of symptomatic ischemic heart disease. The earliest of these studies omitted from consideration important factors other than physical activity, and data were not subjected to multivariate analysis.^{3,4} More recent efforts⁵ show better experimental design. Results have varied, but one may conclude from a review of the literature that physical inactivity is suggested as a risk factor by a significant body of evidence.^{6,1} Several investigators have physically trained large numbers of cardiac patients.^{7,8,9} Unfortunately, prospective studies of the protective effects of physical exercise in these groups have not yet been reported. When available these data will require scrutiny to assess the effects of exercise itself as opposed to risk factor control achieved concomitantly in the group setting.

Physiological and metabolic changes can regularly be demonstrated in human subjects and animals after physical conditioning. Mitochondrial enzymes and glycogen stores increase, and the respiratory quotient shifts toward increased carbohydrate utilization.¹⁰ Cardiac muscle mass increases. Cardiac output at maximal exertion and the extraction of oxygen by working muscles are enhanced by training. These changes combine to increase maximum oxygen uptake. Intensive training reduces pulse rate, blood pressure, and pressure-rate product at submaximal

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exercise levels. The consequent reduction in myocardial oxygen demand (MVO_2) may protect against ischemic myocardial damage. During exercise, lower circulating catecholamine levels in trained subjects may also reduce MVO_2 .¹¹ The belief that intercoronary collateral vessels increase in number or size is substantiated only by the work of Eckstein in dogs.¹² Controlled angiographic studies in humans with ischemic heart disease have not yet been done.

One must recognize that circulatory changes, though valid indices of conditioning, are not necessary measures of protective effect. If exercise is protective the necessary dose had not been defined. However, differences between active and inactive study groups amount to several hundred calories daily of energy expenditure,¹³ and periods of daily aerobic exercise appear necessary.⁵

The New Britain Program

With the foregoing facts and postulates in mind, a cardiac rehabilitation program was designed for the New Britain community. An initial group was formed of patients recovering from myocardial infarction. In time, patients with angina pectoris and those convalescing from aortocoronary bypass surgery were added. The program was begun with outpatient interval exercise supervised by a physical therapist. Soon, inpatients were added and a YMCA-sponsored component was begun after 18 months. At present, all portions of the program are structured around four gradually progressive stages of physical conditioning.

PHASE I. Suitable patients with myocardial infarction are admitted to the rehabilitation program at the request of their attending physicians. A progressive system of mild exercise is begun as soon as the patient is physiologically stable, usually on the second or third hospital day. Candidates may be rejected on account of extreme age, intercurrent disease, or persistent cardiac symptoms. A physical therapist supervises mild exercises progressing through 12 stages. This system, adapted from that of Wenger,⁹ begins with passive range of motion and progresses to calisthenics requiring $2\frac{1}{2}$ cal./min. The patient climbs a flight of stairs on the last few days prior to discharge. As in all portions of the program, exercises are isotonic rather than isometric; and involve legs and trunk rather than arms and shoulder girdle. This technique increases blood pressure and pulse less at comparable external work loads.

PHASE II. Several days after discharge, the cardiologist sees the patient briefly to screen out candidates unsuitable because of arrhythmia, uncontrolled hypertension, heart failure or unstable angina. Suitable candidates are instructed by the physical therapist in four basic exercises requiring up to 3 calories per

minute (Figure 1), and are shown how to monitor the carotid pulse. The therapist records the pulse after one minute of each exercise. Patients perform the exercises twice daily at home and return to therapy weekly to perform them under observation. Patients keep exercise pulse rates below 110/minute, and report any irregularities of the pulse. Daily walking exercise is also prescribed at this time and ranges up to 2 or 3 miles per day. Phase II continues until 12 weeks after the infarct, at which time a stress test is administered.

PHASE III. A successful stress test establishes patient safety during exertion, and allows the cardiologist to prescribe a target heart rate (THR). In Phase III, participants attend one-hour sessions thrice weekly in the Department of Physical Medicine. There, a cardiovascular-trained nurse supervises approximately 20 participants as they perform calisthenics and aerobic interval bicycle exercise at their THR's. Six types of calisthenics are done for one or two minutes apiece, alternating with rest intervals which allow recovery to near-basal heart rates. These exercises require up to 8 calories per minute. Aerobic exercise is done on the ergometer at a resistance which raises the pulse to the THR. 3-minute intervals are separated by rest periods. Most participants add a fourth 3-minute period of treadmill exercise at THR. The nurse records BP and pulse at the outset of each exercise session, and during the 2nd bicycle exercise period. Any symptoms, arrhythmias, or blood pressure aberrations are noted in monthly progress reports to each patient's private physician. The nurse may independently alter the target heart rate, or this may be done by the cardiologist after followup bicycle stress tests which are done every 3 months. After Phase III, patients have 3 options. (1) They may enter Phase IV of the program, the H.E.A.R.T. program of the New Britain YMCA, 9 months after the infarct. (2) They may remain in Phase III up to a year if they have elected not to move on to the YMCA program. (3) Patients who wish to continue a conditioning program but are unsuitable for the more strenuous YMCA exercise may continue in Phase IIIA. This phase is identical to III, but meets twice weekly.

PHASE IV. The H.E.A.R.T. Program (Phase IV) was developed jointly by New Britain General Hospital and the New Britain YMCA. The post-coronary participant enters Phase IV after the third Phase III stress test, often with a revised THR. YMCA sessions bring together a group of 20 to 25 participants for 50 minutes thrice weekly in the gymnasium, under the supervision of a cardiovascular nurse and a member of the YMCA physical department. The program's cardiologist and another physician frequently exercise with the group. Pulse rates are recorded at the beginning of each session and blood pressures each month.

counts/minute

Energy Cost
calories/minute

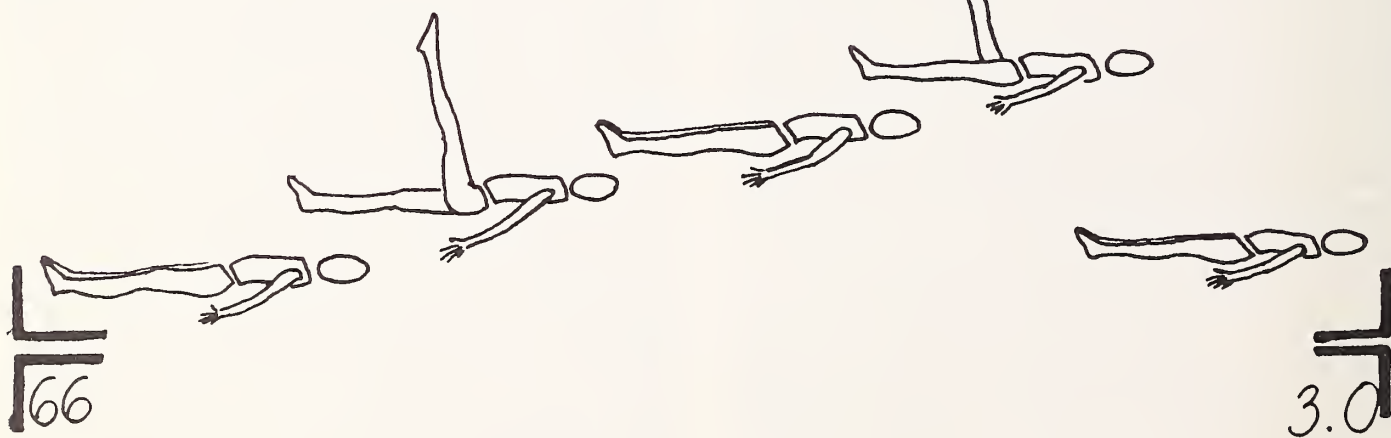
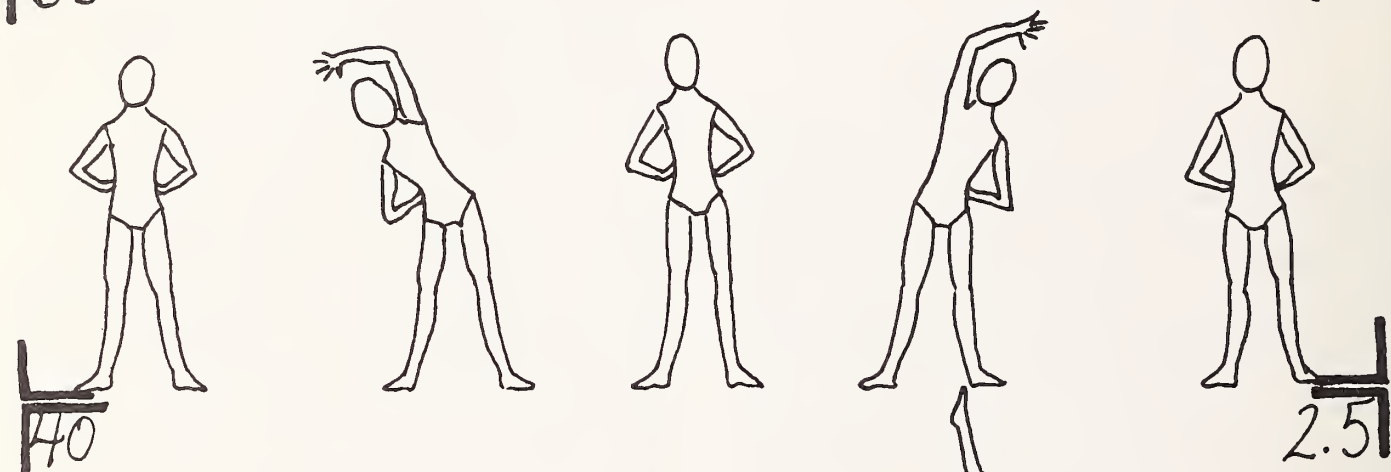
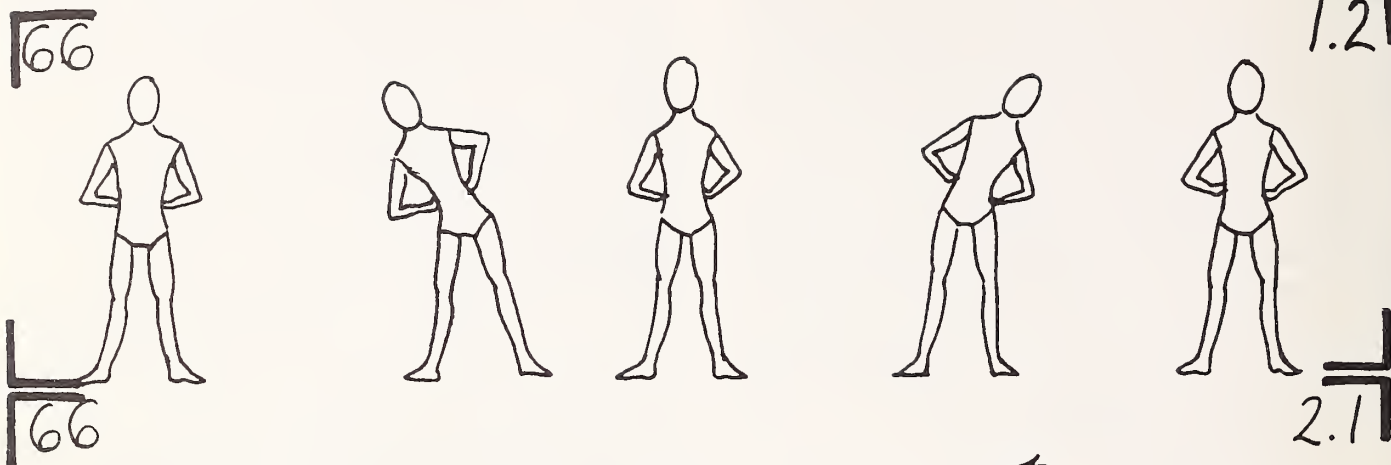


Figure 1
Phase II Exercises

Participants begin the day's workout with a 20-minute walking-jogging alteration according to individual stamina and symptoms. Distances vary from ½ to 2 miles, and the nurse records the pulse rate and any irregularities after the last lap. The group then forms a large circle, and the staff leads calisthenics for ½ hour. Calisthenics consume up to 5 calories/minute and jogging approximately 8 calories/minute. Several times during each session, the nurse calls on the participants to check their pulses. Heart rates are also recorded after a standardized 2-minute hopping exercise. Progress is assessed in terms of stamina, symptoms, exercise heart rates, psychological and social adaptation, and reported monthly to each participant's physician. Stress testing is required at 6-month intervals. Participants may remain in the YMCA H.E.A.R.T. program indefinitely.

Psychological Measures

Early attention to patients on the cardiovascular unit, and the supportive group environment of Phases III and IV are effective against reactive depression, anxiety, hypochondriasis and excessive denial. In addition, group psychotherapy is offered to all participants as a routine component of the program. Approximately 40 patients have participated in 10-session series conducted by workers from the New Britain Mental Health Clinic. Hospital social workers assist patients with family and job adjustment, and a variety of financial and logistical problems.

Risk Factor Control

Patient education in the prevention of coronary disease is begun in the cardiovascular unit and reinforced frequently in later phases. A hospital dietitian consults with patients individually prior to discharge and meets monthly with groups to assist in planning low-fat and calorie-restricted diets. Repeated visibility in a group setting encourages weight loss and much dietary information is exchanged informally. Most smokers abstain from tobacco from the time of their infarct. Staff encouragement and group reinforcement effectively maintain non-smoking in the majority. Blood pressure is monitored repeatedly and control is required for participation in the program.

Stress Testing

Periodic stress tests are required for continued participation in the program. The patient's interval history is assessed and a brief physical exam is performed by the program's cardiologist. Medications are not discontinued but an effort is made to test at a fixed interval following propranolol doses. The patient is seated on a bicycle ergometer and an anesthesia sphygmomanometer cuff is placed on the arm. A

single EKG lead is monitored with electrodes on the vertebra prominens and cardiac apex. EKG tracings and blood pressure readings are taken at rest and during one-minute exercise stages at progressively higher resistances at a 70-rpm cadence. Exercise is stopped if angina or dyspnea become intolerable, if leg fatigue or exhaustion supervene, or if hazardous arrhythmias develop. Patients are encouraged to exercise to their limits but are not required to attain truly maximal stress levels. Immediately following exercise, the heart is examined for ischemic gallops and murmurs. Blood pressure and EKG tracings are then followed each minute through a 5-minute recovery period. The cardiologist decides on the basis of test results whether the participant may safely continue in the program and renews or modifies his written exercise prescription. Tabular records of each participant's series of stress test results form one basis for assessing progress.

Safety

Physical conditioning of cardiac patients requires meticulous attention to safety. Initial screening by the cardiologist eliminates many high-risk patients. Periodic stress testing plays a similar role and ensures realistic exercise prescription. Continuing surveillance has led to treatment of arrhythmias and hypertension in a number of instances.

The hospital's resuscitation team is available for Phases I, II, and III. A defibrillator is on hand at both the hospital and YMCA and a full set of emergency medications is moved into the YMCA gymnasium for each session. All participants are instructed in life support and the evacuation plan is rehearsed with YMCA personnel and police. The effectiveness of the system is attested by successful treatment of two participants with harmless arrhythmias and two with cardiac arrest.

Administrative Aspects Personnel

In order to establish a cardiac rehabilitation program, certain basic roles must be filled. Phases I and II require a physiotherapist or the equivalent. Cardiovascular nurses supervise Phases III, IIIA, and IV and maintain a therapeutic group environment. Exercises at the YMCA are led jointly by nurse and physical educator. We require that two staff members be present at all YMCA sessions to assure safety. All personnel have experience with exercise work and training in CPR.

An essential feature of the program is frequent crossover between traditional health-care roles. Dietitian, social worker and psychotherapy group leader roles might be partially filled by other personnel in a smaller community. A physician carries out exercise-testing, exercise prescription, screening, and integra-

tion of the program with private medical care. In the future a physical educator or nurse-practitioner might perform these duties under a physician's supervision. It is not necessary that the physician be a cardiologist.

Monthly Meeting

The entire program staff assembles monthly for a review of each patient's progress and for decisions on management. This regular multi-disciplinary event allows critical evaluation, realistic goal-setting and planning based on a variety of insights.

Cost

Phases I and II are paid for by hospitalization insurance. Phase III is covered by major medical insurance and by most ordinary policies including Medicare. There is a five dollar charge for each session of Phases I through III and IIIA. Phase IV costs \$15 per month in addition to a \$12 annual charge for YMCA membership. Carriers vary in their coverage of Phases IIIA and IV and it is clear that attitudes of third party payers have not yet crystallized with regard to cardiac rehabilitation. The first year's therapy after a myocardial infarction costs:

Phase I	\$5	x	21	=	\$105
II	\$5	x	9	=	45
III	\$5	x	78	=	390
IV	\$15	x	3	=	45
3 exercise tests at \$40				=	120
YMCA membership				=	<u>12</u>
					\$717

Subsequent yearly costs are:

2 exercise tests at \$40	=	\$ 80
11 months' program charges at \$15	=	165
YMCA membership	=	<u>12</u>
		\$257

These figures are well below those for commercially-sponsored rehabilitation programs and reflect our efforts to prevent exclusion of participants on account of expense. Nevertheless, the program is revenue-producing for both hospital and YMCA.

Physical Requirements

Phases I and II require minimal individual exercise areas. Phase III is conducted with ease in a 18' x 35' space in the hospital's Physical Medicine Department. The entire YMCA gymnasium (110' x 85') is normally used for Phase IV, but a 44' x 24' room suffices as a substitute. Five Schwinn ergometric bicycles are used for Phases III and IIIA and one particular machine is

used for testing. A portable defibrillator was donated by the Heart Association and service clubs and is shared by the YMCA and hospital.

Results and Discussion

Since its inception in 1971, 496 patients have entered the New Britain Cardiac Rehabilitation Program. 439 first entered via Phase I, 21 via Phase II, 35 via Phase III and 1 via Phase IV (Figure 2). Since January, 1973 the average size of Phase I has been 3, Phase II, 8; Phase III, 21; and Phase IV, 20. 74 are participating at present.

Of the 387 patients who entered Phase I in 1971 through 1974, 113 went on to Phase II. Of these 75 went on to Phase III (66%) and 63 remained longer than 6 weeks. 48 of the 75 continued into phase IV, 40 for more than 6 weeks. Though Phase I is valuable for in-hospital instruction and ambulation, these figures indicate that most do not continue into the out-patient program. When out-patient referrals to Phase II are included with Phase I entrants, persistence into Phase III rises to 83%. This typifies the greater motivation of the out-patient-referral group. Many of those entering Phase I were unsuitable and active only briefly. Persistence is increasing with improved selection.

The average Phase IV participant has been with the program for 16.6 months, indicating high persistence. Six of seventy-one current participants entered via Phase I. Phase IIIA has grown to 14 participants since it was begun in March, 1975, and persistence is excellent among this determined group.

The program was enthusiastically welcomed by the Hospital, YMCA, and Heart Association. The concept of cardiac rehabilitation has been warmly supported by most attending physicians and increasing use of the program has resulted in steady growth. Practitioners regularly use the observations of program staff in patient management. Patients are referred both to encourage and to moderate exercise habits. Many have been sent for control of multiple risk factors, others primarily for group psychotherapy. Program size will eventually be limited by personnel and space. For effectiveness and safety, single exercise groups are limited to 20 in Phase III and 25 at the YMCA. We enthusiastically endorse the linkage of hospital and YMCA in a gradually progressive program for the patient with a recent infarct. Six months of careful assessment during supervised ergometer exercise (Phase III) allows us to identify and treat or eliminate unacceptably high-risk patients. As a result, 8900 participant-hours of exercise have been performed at the YMCA with 2 minor arrhythmias and two successfully-managed cardiac arrests.

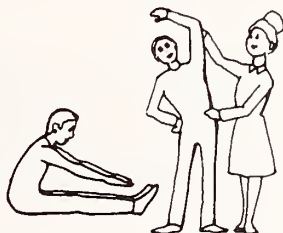
PHASE I Inpatient	PHASE II Early Out-patient	PHASE III Late Out-patient	PHASE IV YMCA
			
Total Entrants: 439	Direct Entry: 21	35	1
1971-74 Entry: 387	Carried On: 113	75	48
Avg. Enrollment: 3	8	21	20

Figure 2
Patient entry by phase, persistence in program and average enrollments

The program has been a very worthwhile community enterprise, cutting across departmental lines and focusing the enthusiasm of many health-care professionals in a team effort. As a teaching device, it displays coronary prevention in a highly visible and positive fashion. Above all, it returns the cardiac patient to a full life and by modifying risk factors offers the key to secondary prevention of ischemic heart disease.

Summary

In this report we describe the New Britain Cardiac Rehabilitation Program and summarize the rationale upon which it is based. We indicate its value in the control of multiple coronary risk factors and as an aid to psychological adaptation after myocardial infarction. We describe the administration of our program including personnel, safety, costs, and patient flow. Our observations on participants' cardiovascular conditioning will be reported subsequently.

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Pyogenic Abscess of the Liver

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ABSTRACT—Pyogenic liver abscess may be increasing in frequency. In a recent five-year period, ten patients with liver abscess were treated in the Saint Francis Hospital. The etiologies of these abscesses were varied, including several where no antecedent surgery had been performed.

Where the diagnosis was entertained and suitable studies performed, the correct diagnosis could usually be established. The only satisfactory treatment in our experience was surgical drainage combined with intensive antimicrobial therapy. The patients so treated did well.

Based on our experience, it appears important that liver abscess be considered in the differential diagnosis of fever of unknown origin in the postoperative period, and even in certain selected cases where no previous surgery has been performed.

Untreated hepatic abscess is a life-threatening disease. In the past, the diagnosis of this condition was rather infrequent in life and because of this, the mortality rate in untreated liver abscess was extremely high. As late as 1965, in a series of 70 cases, the mortality rate approached 85%.¹ In the situation where the abscess was never treated surgically, the mortality rate was 100%. In a recent series, Pitt and Zuidema² reported on 80 patients treated at the Johns Hopkins Hospital over a 30-year period. All of these patients were treated surgically and in this situation, the mortality rate overall was approximately 60%.

A significant aid in diagnosis has become available in recent years. It appears that the liver scan is a highly accurate means of diagnosing this condition, and when used widely, it seems to lower the mortality rate. In the present series, this modality was used and the results were extremely impressive. It may be that as this technique is used more widely the diagnosis will be established more readily and suitable therapy instituted.

Clinical Material

From 1970 to 1974, a total of ten patients with pyogenic liver abscesses were treated at Saint Francis Hospital. The hospital is a 650-bed community facility; during this same period, there were approximately 75,000 admissions to the hospital. Therefore, we had

an incidence of approximately one patient with hepatic abscess in every 7,500 admissions.

The age of the youngest patient treated was 24 and the oldest was 82 with a median age of 56 years. Males were in the preponderance with eight patients out of ten.

Table I

X-RAY PROCEDURES

Procedure	# Cases	Positive Findings
Liver Scan	8	8
Celiac Ang	4	4
BA Enema	3	2
GB Series	5	2
GI Series	6	2
IVP	3	0
IVC	3	0

It is worthwhile to emphasize the importance of fever as a symptom in this condition. The degree of fever varied from 100° elevations to high-spiking fever that was clearly indicative of a serious pathologic process. In addition, abdominal pain, usually right upper quadrant, was frequent in a significant percentage of patients. Shoulder or pleuritic pain was also seen on occasion, and frequently, the patient would have evidence of a paralytic ileus as a result of this condition, although this was not invariably present. Standard laboratory evaluations generally revealed evidence of systemic infection with a leukocytosis in most patients and anemia being present in a significant number. Standard liver tests usually, but not invariably, revealed abnormalities, and the blood culture was positive in 50% of the patients treated.

Of all the radiologic examinations, the liver scan was far and away the most important. It was done in eight patients and was positive in all eight. (Table I) Angiograms were only done in four patients and hypovascular areas were demonstrated in all instances. Clearly, this is another test that will become increasingly valuable as a diagnostic tool.

Regarding the etiology of the liver abscess, there were four patients with pre-existing biliary tract disease, two with diverticular disease of the colon, and four in which no obvious cause for the abscess could be determined. Associated general medical conditions

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Table II

ASSOCIATED CONDITIONS

<i>Disease</i>	<i># Cases</i>
Diabetes Mel	5
Biliary Tree	3
Diverticulitis	2
Liver Cirrhosis	2
ASHD	2
Hypertension	2

included primarily diabetes. (Table II). The time interval between the day of admission and the day of surgical exploration ranged between ten days and one

Table III

TIME BETWEEN ADMISSION AND SURGERY

<i>Time</i>	<i># Cases</i>
1 Week	2
2 Weeks	3
3 Weeks	4
4 Weeks	1

Median Interval—18 Days

month with an average of 18 days. (Table III). All patients but one were explored. In that one patient, diagnosis was not established until post-mortem ex-

Table IV

THERAPY AND ABSCESS LOCATION

<i>Therapy</i>	<i>Drainage & Antibiotics</i>	
	<i>Antibiotics Only</i>	
	9	1

<i>Location</i>	<i>Right</i>	<i>Left</i>	<i>Multiple</i>
<i># Cases</i>	4	4	2

amination. Eight patients had solitary abscesses and two patients had multiple abscesses. (Table IV). The micro-organisms involved varied, and no pattern could be determined. In addition, there were several patients who had negative cultures, presumably being related to long-term antimicrobial therapy prior to surgical drainage. (Table V).

Table V

CAUSE OF ABSCESS AND ORGANISM

<i>Cause</i>	<i>Blood Culture</i>	<i>Abscess Culture</i>
Cholangitis	E. Coli	E. Coli
Cholangitis	Gram +	Anaerobes
Cholangitis	Not Taken	Not Taken
CA Head Pan	Negative	Kleb-Pseudom
Perf. Diver.	Clost. Perf.	Clost. Perf.
Perf. Diver.	Bacteroides	No Results
6 Mo. P.O. Gast.	Not Taken	Negative
? Syst. Diss 2 Mo.		
P.O. Tooth Ext.	Not Taken	Alpha Strep.
Not Known	Not Taken	Pseudomonas
Not Known	Not Taken	No Results

All patients except the last three had previous abdominal surgery related to GI or Biliary Tract.

Results

In the seven patients who had solitary abscesses, drainage plus appropriate antimicrobial therapy resulted in good recovery from this condition. There were two additional patients who had multiple abscesses treated surgically and both died. In one additional instance, the abscess was not diagnosed until post-mortem examination.

Discussion

Hepatic abscess has been a clinical entity of life threatening importance. It has consisted of three general types: bacterial, parasitic, and mycotic. In this series, we have presented patients with the bacterial type.

Hepatic abscess consists of two general varieties: solitary ones, usually limited to one hepatic lobe and amenable to surgical drainage; and multiple abscesses throughout both lobes and probably not amenable to surgical drainage.

In this series, 80% of the abscesses were solitary. Incidence of solitary lesions has increased relatively during the past fifteen years, while there has been a progressive decrease in the number of multiple abscesses in the same period. This most likely is the result of effective antibiotic therapy of the primary non-hepatic disease and its complicating sepsis.

The reported incidence of hepatic abscess is between 0.007% to 0.04% of hospital admissions. In our series, the incidence is one case in every 7,500 admissions. (0.013%). Most authors agree that the average age of the patient with hepatic abscess is between 50 and 60 years. In our series, the youngest patient was 24 and the oldest was 82 for a median age of 56. Most series indicated a slight preponderance of males as compared with females. Our ratio was 4 to 1.

The diagnosis of liver abscess is based primarily on clinical observations, the symptoms being due to generalized septicemia. The average duration of illness prior to hospitalization varied. In Joseph, Kahn, and Longmire's report,³ it was between six days and five-and-a-half months. The average reported in the past was approximately two months. In our series, no correlation has been made for the duration of illness before hospitalization, but the duration of hospitalization before any surgical intervention was between one week and one month with a median interval of eighteen days.

In the Joseph, Kahn, and Longmire series,³ the most common complaints were fever and chills, in 78% of cases. The most common presenting complaints in the Ribaudo and Ochsner series⁴ were right upper quadrant pain, nausea, and vomiting, weakness and weight loss. In our series, right upper quadrant pain, fever and chills were the most common symptoms.

Clinical jaundice occurred only in one patient in this series, but serum bilirubin was elevated in half of the patients. In the Butler and McCarthy series,⁵ jaundice was present in all multiple abscesses and in 25% of cases with a solitary abscess. Most of the authors agree with that, but we found one incidence of jaundice in a patient with a solitary abscess, because of cholangitis.

The study of patients with liver abscess usually shows significant leukocytosis, anemia, and abnormal liver function studies.

Low serum albumin, elevation of serum B₁₂, and low serum urea has been mentioned as indicative of a poor prognosis. Butler and McCarthy⁵ point out that if the function of the liver is depressed by an abscess, the albumin synthesis suffers early, and if a large area of liver is occupied by the abscess, this leads to a sustained fall in serum albumin levels. If it drops below 2 gm per 100 ml, the prognosis is grave.

Elevation of the serum levels of vitamin B₁₂ due to liberation of liver stores as hepato-cellular destruction proceeds is probably the most important feature of liver abscess, but levels may not be raised in the very old, if the liver stores are already depleted.

Radiological findings in this series correspond with those reported in the literature and include elevated right diaphragm, right pleural effusion, and collection of gas in the right upper quadrant not related to the gastro-intestinal tract. The special studies, such as, IVP, IVC, barium enema, gallbladder and gastro-intestinal series, were only helpful if the disease causing the abscess involved those organs being investigated.

There is general agreement in the literature that the liver scan is most helpful as a diagnostic test and is essential for both early diagnosis and accurate drain-

age, as well as follow-up care. Our series demonstrates hepatic photoscanning to be accurate in 100% of cases.

Ultrasonic scanning was used by Butler and McCarthy.⁵ They showed that it has a major advantage over the isotope scanning in that it can clearly distinguish between solid and fluid lesions, thus, separating abscess from tumor.

Hepatic angiography is also helpful and splenoportography has also been used. These studies may be indicated, if scanning is not successful.

Certain conditions were associated with this disease; diabetes mellitus was highest on the list with 50% of the total number of cases. Two of the five patients with diabetes died. Arteriosclerotic heart disease and hypertension were also associated with liver abscess.

The organisms identified and grown by culture showed 50% incidence of gram-negative rods and 50% incidence of gram-positive rods.

In most reported series, cultures from the material of pyogenic abscesses were positive in more than 50% of the cases. The most common source of infection in the past has been gram-negative organisms. Sherman and Robins⁶ in 1943 found 64% to have been due to *E. coli* and McFadzean⁷ reported *E. coli* as the offending organism in 57% of cases. The most recent reports indicate that the gram-positive cocci are an increasing cause of hepatic abscess.

Futch, Zikria, and Neu,⁸ describing bacteroides liver abscesses, found a general increase in anaerobic infections in a variety of clinical settings. It is interesting to speculate that some of the increase in bacteroides infections of the liver may be due to primary mixed infections that have responded only partially to antimicrobial therapy. *E. coli*, *Klebsiella*, and anaerobic Streptococci for that matter will respond to the antibiotics of the Cephalosporins. The widespread use of a combination of an aminoglycoside, such as, Kanamycin or Gentamycin with Cephalosporin, eradicates the majority of bacteria, leaving only bacteroides. The justifiable caution that is used in the administering of Chloramphenicol would also account for our seeing these organisms in liver abscess, since many of these organisms are currently resistant to tetracycline antibiotics, which have also been used widely in the treatment of infections that predispose to seeding bacteroides into the liver.

The primary source of infection in our series was intraperitoneal in 70% of the cases. Four cases had some type of biliary obstruction; two patients had diverticulitis. In one case, the abscess appeared six months post-gastrectomy, and in three cases, the abscess was thought to be cryptogenic.

In the Joseph, Kahn, and Longmire series,³ the source of infection was nearly equally divided be-

tween intraperitoneal disease and generalized septicemia.

In their earlier report, Ochsner, DeBakey, and Murray⁹ reported that in 10% to 30% of their patients, pyogenic abscess was secondary to appendicitis and pylephlebitis. Altemeier, Schowengerdt, and Whitley¹⁰ in their series showed that in 80% of the cases, the primary source of infection was detected and heading the list was extrahepatic biliary tree disease. In the same series, they reported eleven cases in children with only three having abscesses amenable to surgical drainage. In one, the abscess was a complication of a severe regional enteritis.

In the other two children, the etiology was obscure. Of the remaining children, three had associated lymphoblastic leukemia, two were premature infants with associated infection, one had extrahepatic biliary atresia, and three others died of septicemia originating from an extrahepatic source.

Most authors recommend open surgical drainage for the treatment of pyogenic abscess. The open drainage technique has different approaches, including posterior extra-serous anterior transperitoneal and anterior extraperitoneal. McFadzean and associates⁷ reported fourteen cases treated successfully with percutaneous closed catheter drainage.

Goldsmith and Wei-Fan Chen¹¹ stressed the point of appropriate surgical drainage and noted that if the abscess is surgically treated, complications following the operation are most frequently due to inappropriate surgical drainage. Goldsmith¹¹ believes in exploring the liver abscess through the peritoneum. This technique would allow the surgeon to palpate the entire liver and to recognize the intraperitoneal disease causing the abscess and treating it at the same time. The fear of peritoneal soiling with an intraperitoneal approach can be minimized by carefully walling off the liver with gauze pads and by using suction catheters.

From the experience at Saint Francis Hospital, it appears that transperitoneal drainage is the preferred technique because of its greater flexibility, especially if other important surgical conditions are encountered.

We reported an overall mortality of 30%. Our mortality rate in the solitary abscess is 13% and 100% in multiple abscesses. We have experienced no mortalities for the solitary abscess treated surgically. The only death report in the solitary abscess category was in a patient who died before surgical intervention. At autopsy a liver abscess was found.

Warren and Hardy¹² reported a mortality rate of 30% for solitary abscess and 80% for multiple abscesses. In 1965, Pyrttek and Bartus¹ reported a mortality of 88% in their series of 42 patients. McFadzean and associates⁷ are in favor of aspirating solitary abscesses and reported 100% survival of their patients. In 1972, Sabbai, Sutter, and Finegold¹³ reported an overall mortality rate of 24%.

The high mortality associated with pyogenic liver disease can only be diminished through early diagnosis and expeditious surgical intervention. This, in turn, can be achieved only by a constant clinical awareness of the liver abscess and knowledge of its probability in any given case of sepsis.

Summary

Ten cases with pyogenic liver abscess are presented. Obscure and persistent fever with right upper quadrant pain were the hallmarks of this disease, which can be diagnosed most reliably by hepatic scanning. Prompt surgical drainage and antibiotics are the treatment of choice. With aggressive appropriate therapy, the mortality can be decreased.

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Superiority of Helium-Air Flow-Volume Curves to Routine Spirometry in the Preoperative Pulmonary Evaluation of Teenage Scoliotics

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ABSTRACT—To assess obstructive small airways disease in teenage idiopathic scoliotics, twenty consecutive patients free of known causes of obstructive small airway disease, were studied. Spirometry, helium-air flow curves and point of identical flow (PIF, VisoV) were determined before and after a bronchodilator was administered. Seventeen “normal” patients were similarly studied as controls.

Obstructive small airway disease was demonstrated in eight (forty percent) of the patients by helium-air flow curves and PIF that was not identified by spirometry alone. Six of these eight patients (seventy-five percent) demonstrated improvement after a bronchodilator.

Key Words: Flow-volume curves
Scoliosis
Points of identical flow
Pulmonary function

Flow-volume curves,^{1,2,3} helium-air flow curves and point of identical flows (PIF, VisoV)^{4, 5, 6} have been established as sensitive parameters for the detection of obstructive small airway disease. The current study

was undertaken after preliminary unpublished data revealed their possible superiority to routine spirometry in the detection of early obstructive small airway disease in the idiopathic scoliotic teenager.

Nickel and Renshaw in 1957⁷ pointed out the problems encountered when operating on patients with spinal deformities and reduced pulmonary function. The teenage scoliotic, or any scoliotic, represents a particular risk when they become surgical candidates.⁸ Restrictive pulmonary phenomenon are well established in teenage idiopathic scoliotics,⁹ secondary to vertebral column and bony thoracic deformities. In the past, obstructive phenomenon have not been generally recognized nor described in the teenage idiopathic scoliotic.⁹ Surgical correction of the teenage scoliotic usually entails spinal fusion and Harrington rod insertion. Postoperatively, the patient has a seven to ten day period of complete bed rest while confined to a bi-valved Risser localizer cast. Protracted bed rest in the patient with restrictive and obstructive small airway disease is potentially capable of

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Table 1
DESCRIPTIVE DATA AND RESULTS OF SPIROMETRY AND POINTS OF IDENTICAL FLOW, BEFORE AND AFTER BRONCHODILATOR IN TWENTY CONSECUTIVE TEENAGE IDIOPATHIC SCOLIOTICS

Pt.	Thoracic Curves	FEV1	%	%	% Pred.	%	Spirometry After Bronchodilator	PIF	PIF
		% FVC	Pred. FEV1	Pred. MMEF		Pred. TLC		% VC Before Bronchodilator	% VC After Bronchodilator
1	T-53°	82	81	68	78	79	No Improvement	10	10
2	T-64°	97	60	89	56	55	No Improvement	33	0
3	T-30°	81	49	54	52	48	No Improvement	23	20
4	T-60°	82	28	32	32	29	No Improvement	50	50
5	T-72°	81	72	66	54	61	No Improvement	6	6
6	T-20°	95	101	124	106	70	No Improvement	21	7
7	T-52°	71	68	48	65	81	Improvement	10	0
8	T-55°	88	67	88	65	65	No Improvement	0	0
9	T-57°	83	88	75	76	79	No Improvement	17	0
10	Kyphos	81	86	65	74	68	No Improvement	0	0
11	T-28°	87	65	91	67	61	No Improvement	27	0
12	T-52°	70	89	90	73	64	No Improvement	0	0
13	T-55°	80	84	107	95	79	No Improvement	5	0
14	T-53°	83	80	90	103	69	No Improvement	12	0
15	T-34°	86	90	102	107	72	No Improvement	0	0
16	T-60°	42	32	44	54	58	No Improvement	26	0
17	T-49°	61	57	49	62	75	No Improvement	6	0
18	T-74°	86	79	85	84	74	No Improvement	20	0
19	T-53°	72	73	60	76	73	No Improvement	21	0
20	T-55°	117	84	110	74	80	No Improvement	7	0
Avg. 67								Avg. 14	Avg. 4

leading to atelectasis and other pulmonary complications, unless preventive and corrective measures are taken. Therefore, the existence of obstructive small airway disease, if present, should be verified before surgical correction is undertaken. Also, it is important to know if the obstructive phenomenon respond to bronchodilator therapy as measured by increased maximum expiratory flow volumes (MEFV) and/or a simultaneous decrease in PIF (VisoV). Zapletal, et al.,¹⁰ established ranges for the MEFV curves in teenagers, feeling that in this age group, MEFV could be expressed in terms of total lung capacity (TLC). The value of MEFV curves and PIF (VisoV), as a sensitive and quantitative means of diagnosing early obstructive small airway disease was established by Fox, Hutcheon, and others.^{5, 6}

Materials and Methods

Twenty consecutive teenagers with idiopathic scoliosis, whose disease processes had progressed to the point where surgical intervention was indicated, were studied. Patients who smoked, suffered from asthma, hay fever, chronic bronchitis, or had an upper respiratory infection within six weeks, were excluded. The methods followed those previously established for determining flow-volume curves breathing air and helium-oxygen mixtures.^{5, 6}

Routine spirometry was done on a computerized Collins Modular Lung Analyzer (P-1222). The TLC was determined by the helium equilibration method of determining functional residual capacity (FRC).

In addition, seventeen teenage "normals" were subjected to the same studies in the same sequence.

CASE NUMBER 9 (Characteristic of the normal group)

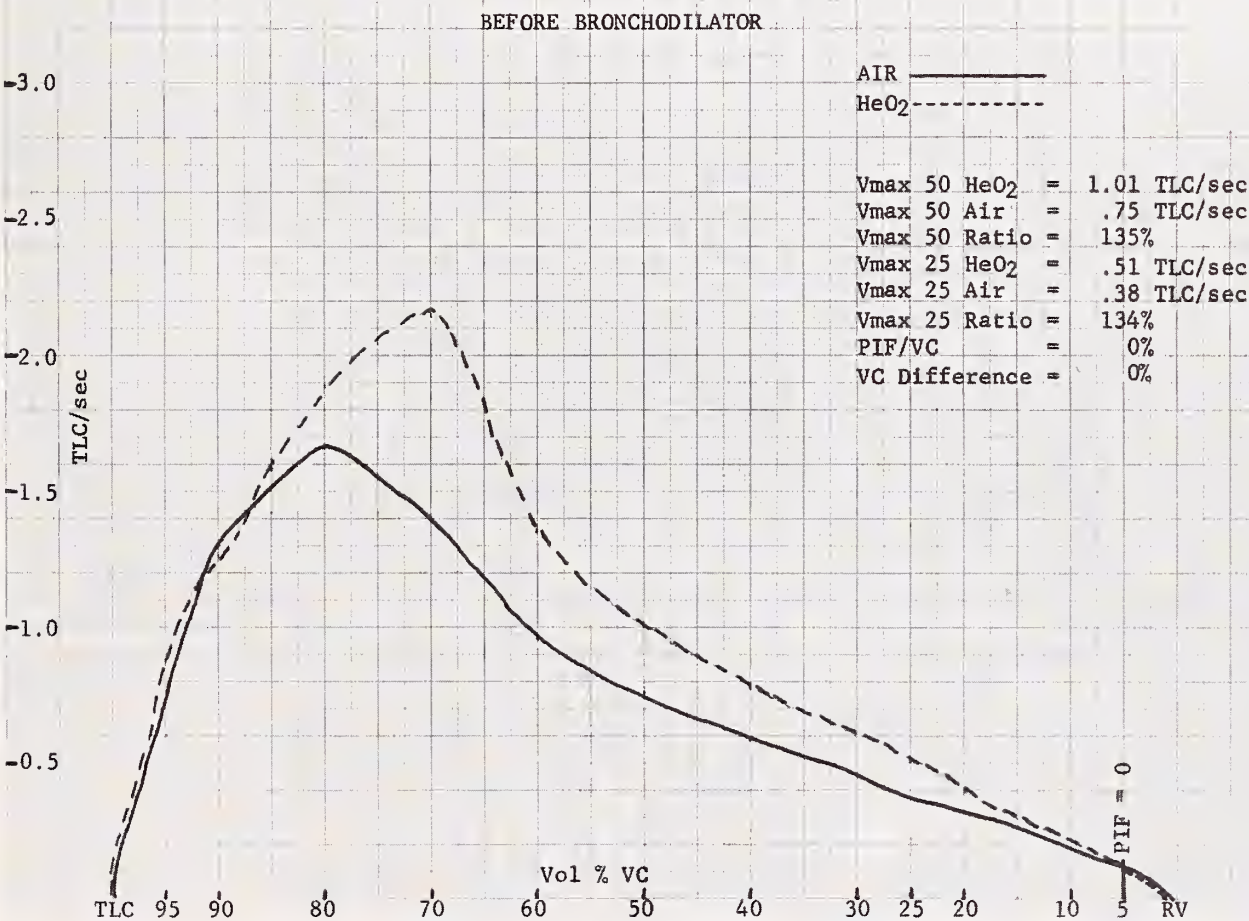


Figure 1
Helium, oxygen and air flow-volume curves in "normal" patient expressed in TLC/sec before bronchodilator.

Results

Twenty teenagers with idiopathic scoliosis and seventeen "normals" were studied. The latter were free of known causes of obstructive small airway disease. Thirteen (sixty-five percent) of the patients (Patients #1, 2, 3, 4, 6, 7, 9, 11, 14, 16, 17, 18 and 19) demonstrated obstructive small airway disease. (PIF's of ten percent of VC or greater, or MMEF of sixty-five percent or less.) If routine spirometry had been employed, the diagnosis could have been made in five (twenty percent) of the cases based on reductions in MMEF (Patients #3, 4, 7, 16 and 17). PIF, as a test of obstructive small airway disease, established the diagnosis in eight (forty percent) of the patients

(Patients #1, 2, 6, 9, 11, 14, 18 and 19), and was not established by spirometry (MMEF).

However, when the diagnosis of obstructive small airway disease was established by spirometry (Patients #3, 4, 7, 16 and 17), all were also verified by PIF (VisoV), except for Patient #7.

Only six patients showed obliteration or improvement of the PIF following isoetharine. The MMEF was improved by isoetharine in only one patient (Patient #7).

Spirometry in the "normal" group of patients fell within the range of normals as previously established in Materials and Methods. PIF's (VisoV) were not seen in the "normals" (Table 2).

CASE NUMBER 9 (Characteristic of the normal group)

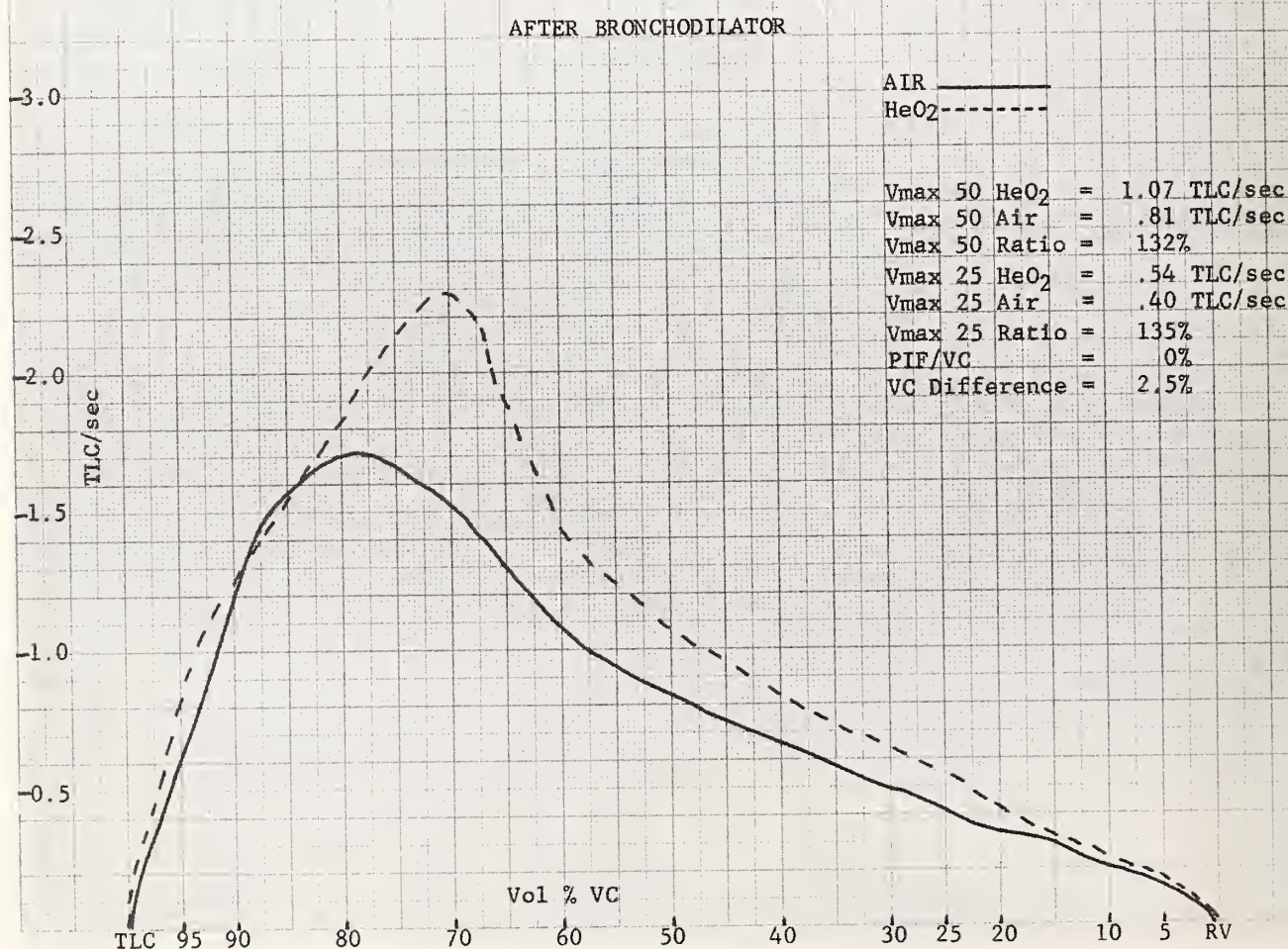


Figure 2
Same patient as in Figure 1 after a bronchodilator.

Discussion

The data obtained in the present study would indicate that helium-air studies and PIF (VisoV) are possibly more sensitive and indicative of early obstructive small airway disease (Table 1), when compared to that obtained with routine spirometry and Vmax 50% of VC breathing air. Further, the response of the obstructive phenomenon to isoetharine (Figures 3 and 4 as an example and Table 1) in six patients is notable.

All patients did not respond to a bronchodilator in their preoperative testing (Table 1), even though demonstrating obstructive small airway disease. An explanation is not readily apparent. Possibly they can be classified as “non responders”⁴ to bronchodilator therapy.

Table 2
POINTS OF IDENTICAL FLOW, BEFORE AND AFTER BRONCHODILATOR
IN SEVENTEEN “NORMAL” TEENAGERS

Subject	Spirometry	% Pred. TLC	PIF	
			% VC Before Bronchodilator	% VC After Bronchodilator
1	Normal	64	0	0
2	Normal	75	0	0
3	Normal	77	0	0
4	Normal	91	0	0
5	Normal	88	0	0
6	Normal	84	0	0
7	Normal	68	0	0
8	Normal	56	0	0
9	Normal	89	0	0
10	Normal	78	0	0
11	Normal	91	0	0
12	Normal	78	0	0
13	Normal	93	0	0
14	Normal	93	0	0
15	Normal	94	0	0
16	Normal	75	0	0
17	Normal	70	0	0

CASE NUMBER 2

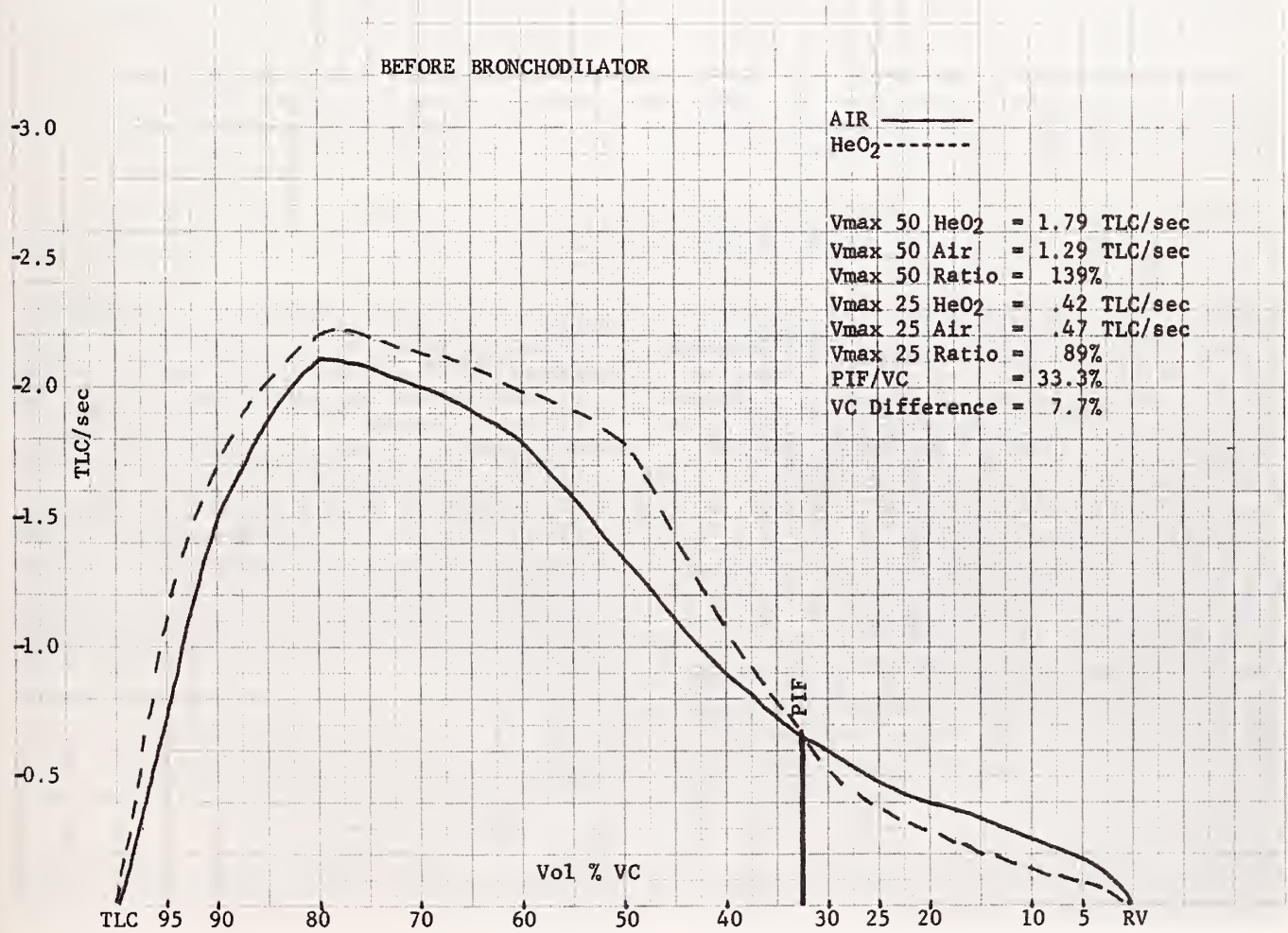


Figure 3
Flow-volume curve before bronchodilator. Patient number 2,
Table 3. Demonstrates PIF.

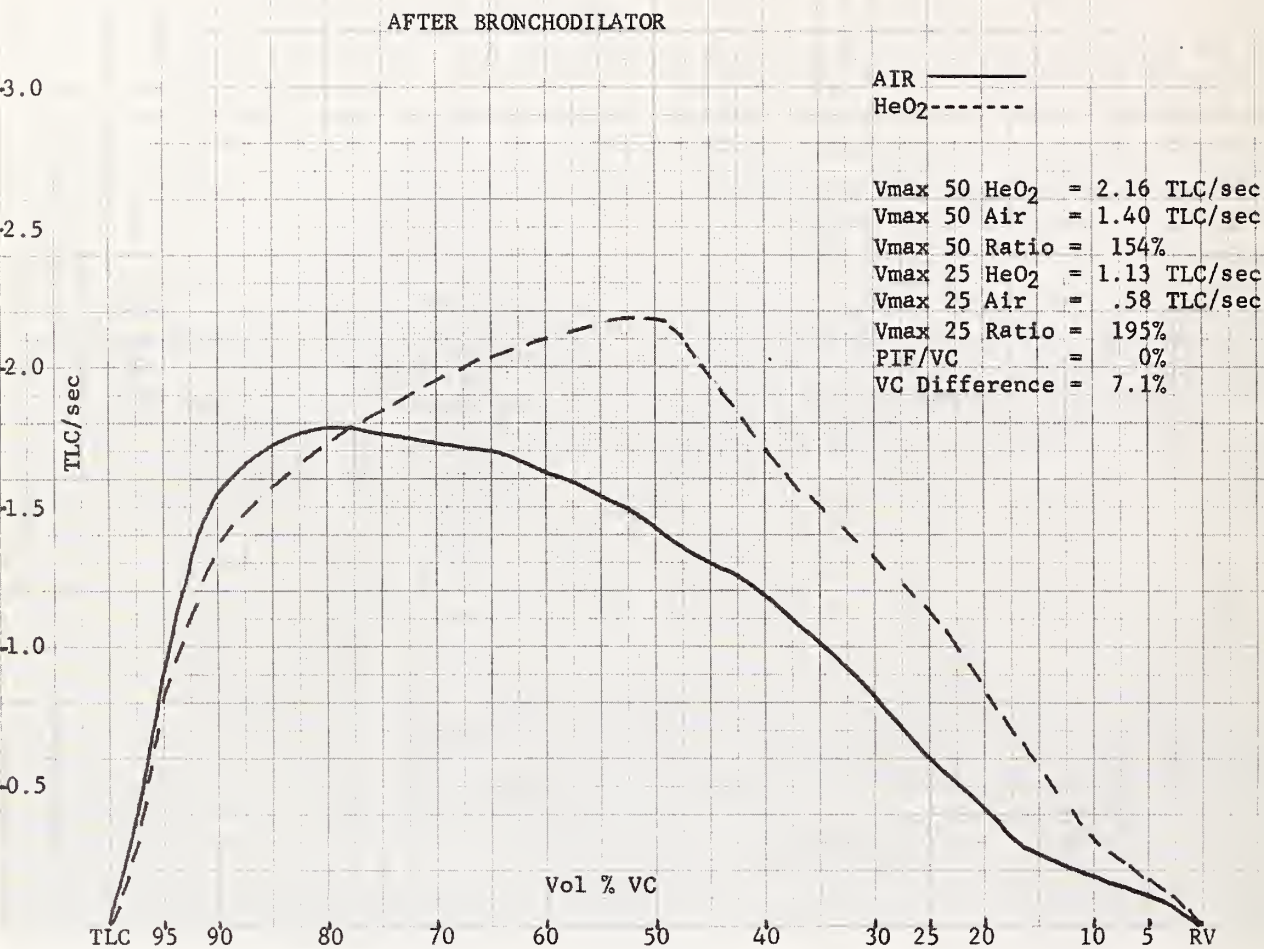


Figure 4
Same patient after bronchodilator as in Figure 3. Shows the beneficial effect of bronchodilator on PIF.

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Medical Practice: A View of the Future

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By the period of 1985-1990, we will have come a long way toward coming to terms with the basic conflict that we have realized, defined and demonstrated over the past decade. This is the conflict between the equity principle that health care is a basic human right and the fact that we do not have the resources to provide for everyone everywhere all of the health care services that are scientifically and technologically possible. It is the classical conflict between the ideal and the practical; the utopian and the realistic.

The compromise will provide greater equity than exists now, but it will necessarily fall far short of the development and implementation of all technological advancements that are scientifically possible and which hold any promise of marginal benefits to health and longevity of Americans, individually or collectively.

Of course this impact of ever increasing knowledge and technology does not affect health care alone. A recent wire service story carried the statement by an American arms' control negotiator that further arms' control agreements soon will be impossible because so many new, highly destructive weapons are being developed that a new weapon can be substituted nearly immediately for any weapon that is limited or abolished by agreement.

While our government has the constitutional responsibility to "provide for the common defense," few Americans expect a majority of our resources to be committed to building every new weapon scientifically possible in order to assure mutual destruction if such a commitment would mean living nearly destitute within a ring of everchanging and ever more expensive armaments.

It is also our government's constitutional responsibility to promote for the general welfare. This has been interpreted to include access to medical care. But similarly, few Americans—when they think about it—and they are beginning to think about it—expect consumption of disproportionate amounts of resources for medical care or health care at the expense of other human wants, and oftentimes, in return for only low marginal benefits at great expense.

The form and substance of medical practice in 1985-1990 will be the direct result of the ebb and flow of the conflict between a prevailing concept of equity and the undeniable limitation of resources. Neither time nor change will stand still, but the kaleidoscopic

picture of that half decade will result from something more than the chance dropping of many varicolored prisms into place. The picture will result from impending decisions about what we need in health care and what health care services we are willing to pay for. We are observing (and hopefully we are more than the passive participants in) the application to health services of basic economic laws expressed by Victor Fuchs and others: 1) There are never enough resources to meet all perceived human wants; 2) Resources have alternative uses; and 3) People have different values that they place on their wants.

What will medical practice be like 10 to 15 years from now?

Patient choice of physician. This principle of freedom of choice will continue—with some limitations. When people purchase insurance or when their representatives bargain for health benefits, they probably will be restricting themselves to a group of physicians—an HMO or an independent practice association or some similar organizational structure. From among this physician group they will be able to choose their own physician.

Physician choice of patient. This principle will continue also, but as it is today, it will be exercised only rarely.

Physician choice of practice location. All physicians will be required to be available to serve two to four years in a specified location or the armed services. But only a few will actually serve. The percentage serving will be less than the percentage of older physicians of today who were in the armed services. If there is no modification—and there will be—of the federal health manpower bill, 16,000 physicians will be available to provide health care in underserved areas. We do not need that many today and because of changes such as fee structure and other methods of physician compensation, we will need fewer by 1985. A lottery probably will result.

Physicians will move more frequently in the next three decades than in the last three decades. They will choose to do so and practice arrangements will make it easier to move several times during their careers.

Physician choice of practice organization. This, after any service obligation, will be a matter of physician choice. There will be fewer in solo practice and more in group practices. Group practices will consist of multispecialty groups and single specialty groups. Many groups will have satellite arrangements. Medical groups, even those which accept few or no prepayment patients, will have increasing responsibilities for

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identified populations. This will be subject to contracts that are bargained with employees, employers, private insurers, or government. Such bargaining will represent an application of market principles and a rejection of the alternative of more severe government regulation. The establishment of more and larger medical organizations will encourage and facilitate physician mobility.

In spite of the declaration of independence from hospital employee status by radiologists and others in the 60's and 70's, by 1985 there will be many more physician employees of hospitals, including primary care physicians as well as the traditional hospital-based specialties. Several factors will bring this about. First, competition resulting from the organization and marketing of total health care packages; second, advances in technology and the prohibitive cost of duplication; third, society's protection of its investment in hospitals; fourth, increased quality monitoring subsequent to increased access to care; fifth, a real surplus of physicians; sixth, the appeal to physicians of graduation to grave security and "the good life," free of entrepreneurial responsibilities; and finally, the obvious but infrequently stated principle: "Hospitals do not have patients. Doctors have patients. Hospitals have doctors."

The number of physicians associated with medical schools will have leveled off or possibly decreased—for several reasons—not least of which is that teaching hospitals are an inefficient and costly way to deliver health services. But, medical schools will be less independent because medical schools, at the insistence of the public represented by their legislators, will be joined in educational efforts with community hospitals and area health education centers.

Income fee arrangements. Physicians will continue to be paid well. Fee-for-service will continue but fee-for-time and salaried positions will have become dominant. Fee schedules will be negotiated, possibly with the federal government but more likely with group purchasers of health services. There will likely be a government role, however, and fees are likely to be as high or higher in rural and other underserved areas as in the suburbs and sunbelt. There will be an effort to pay more and more physicians on a fee-for-time basis. Physicians who specialize in procedures such as endoscopy, cardiac catheterizations, and many surgical procedures no longer will be able to bill \$10,000 for a week's or a couple of days' work. Incidentally, this will make the graduating physician's specialty choice a lot easier than it is today with income potential being such a great variable from specialty to specialty.

As a result of several factors already discussed, physician incomes will become more uniform. Today's industrious general practitioner—without a

gimmick—makes approximately three times (\$43,360) the median industrial wage. The median income for obstetrician-gynecologists is over five times (\$72,380) the median wage, and 42% of the practitioners of this specialty exceed \$80,000 in net annual practice earnings. Only 8% of general practitioners and 7% of pediatricians earn in excess of \$80,000. An educated guess is that in ten years nearly all physicians will make three to four times the median wage—with generally improved working conditions and including generous fringes.

Conditions of practice. American health care and American hospitals and technology will continue to be the standard of the world. But there will be both hospitals and equipment that are a decade or more old, as the regulation of capital expenditures will be strict and effective. Capital expenditure regulation will have been extended to include clinics and physicians' offices. There will be a wider range of choices of expenditures for those institutions that consistently maintain costs below the median. But for the most part, the days of demanding and receiving new equipment immediately will have passed.

There is likely to be a time lag between the discovery on new procedures and equipment and the implementation of new procedures because FDA-like approval of the equipment or procedure following studies of safety and effectiveness will be required.

Hospitals will be running at high occupancy rates and will very likely be operating all departments, including elective surgery, seven days a week. As a result, there will be short waits in some areas for a hospital bed. Hospital use will be both much more intensive and much more expensive because insurance will pay for nearly all *out of* hospital care.

Adequate hospital privileges may be difficult to obtain in some areas. Every practicing physician requires a number of hospital beds. There will be fewer hospital beds per capita and per physician. As a result, in some areas there may be a reluctance to add more physicians to a given hospital staff. Also, the situation whereby in years past physician groups with identified patient populations had difficulty obtaining hospital privileges may be reversed, and 10-15 years hence it may be the solo, fee-for-service physician who has difficulty obtaining sufficient hospital beds.

There will be increased use of other health professionals in part made possible by greater insurance payment for their services and in part by payment of many physicians on the basis other than fee-for-service. But the millenium of greatly increased medical care provided by others than physicians simply will not have occurred for two basic reasons: The great number of practicing physicians and the Ameri-

can citizen's continued expectation that he or she will be cared for by a physician.

Every effort will be made to assure quality of medical care. This will be increased in an effort to institute and maintain market factors in cost control. Because individuals and groups of people will be expected to choose the provider of their care on the basis of competitive pricing, there will be intensive efforts to make certain that they are choosing between *like products*, all of uniformly high quality. Medicine will be practiced much more than now thought possible on the basis of protocols. We will have found by careful quality and outcome assessments that for the most part there are not several equally effective ways of treating most serious illnesses. Self limited illnesses will be *less aggressively* treated than they are today.

As previously implied, patients are likely to be committed to one insurer and/or one group of practitioners and designated facilities for a period of one year. Thereafter, they, more often collectively than individually, will be able to choose again. As a result, it will be necessary for physicians to be responsive to perceived patient needs.

Many regulatory measures have been implied or stated to this point—perhaps much to your distress. But medicine is today one of the most highly but ineffectively regulated of all American industries. In many industries, less regulation is likely. In medicine, I do not foresee *more* regulation—but I do foresee *different* and perhaps *more effective* regulations, so in the remainder of this talk, I will address medical practice 10-15 years hence from the perspective of government regulations, which will continue to profoundly affect medical practices. I also will speak with some frequency, as I have to this point, of market forces and associated incentives and disincentives.

Cost and price regulation. I do not anticipate any long term wage and price controls such as the '71-'73 Nixon experiment with the Economic Stabilization Program. Neither do I foresee total federal payment for health services which would result in the ultimate price regulation of a federal appropriation of a certain number of dollars. Therefore, I do not expect an arbitrary limitation on total expenditures for health. Because of the manpower on line—nearly 600,000 physicians (200 + per 100,000) by 1980, assuming the effective shutoff of foreign physicians—and because of the inevitable march of science and technology, it is likely that we will be spending 10-12 percent of a much larger GNP for health by 1985-90, compared with 8.6% for 1976.

State institutional cost commissions may be operating effectively. There will also be some kind of prospective budgeting for all health care institutions.

But more importantly, the impotent individual pru-

dent purchasers of today will have banded together with other prudent buyers to bargain as a group with organizations of providers for the purchase of services. This will be the incentive for group or associated practices, satellites and increased hospital practice. This structure will limit practice opportunities and, in part, control fees.

Regulation of capital expenditures: If there is effective market place bargaining, the certificate of need laws of the late '70's and early '80's will be modified to be less restrictive. But in order for the market to work, new providers must have access to the market in order to provide competition for established health care institutions. Certificate of need laws which limit the total number of beds and special equipment will make it difficult to build new institutions; and in this way, such laws will tend to stifle the free market and perpetuate the need for these very laws. However, there are at least three other reasons which make it difficult for new providers to enter the market. They are: (1) A large capital investment is required; (2) universal third party payment and/or direct purchasers of services will have contracts with existing providers, and (3) the public has a vested emotional and dollar investment in already existing institutions.

Therefore, hospitals and other major health providers will not come and go like fast food services and gasoline stations. Because of these limitations on the market, states will be regulating hospitals, nursing homes and other institutions in the dual areas of price and quality. This does not rule out the further cost effectiveness of groups or prudent buyers.

Regulation of professional performance. Purchasers will continue to demand to know if a service was necessary, of reasonable quality, and provided in an appropriate setting. This will be accomplished by medical audits in and out of institutions. Individual physician audit profiles will determine privileges and in part determine relicensing by the state. There will be universal reciprocity and federal standards for licensing.

There will be a great emphasis on the effectiveness of medical care. The triad of the seventies, whereby we speak of the cost, availability and accessibility, and quality of medical care, will be modified. By 1985 we will refer to the cost, availability and accessibility, and *effectiveness* of medical care.

It will not be acceptable for a physician or other provider to have done a diagnostic or therapeutic procedure well unless there is a reasonable expectation that the procedure will result in a step toward effectively improving the patient's health. The work of Robert Brook and others will be in full swing in the next decade and thereafter. Does what we are doing make a difference? The highest quality, most expertly

done esophago-gastroduodenoscopy that is not indicated will not help the patient and probably will not be paid for.

Outcome assessment and the cost benefits of health care will be studied and, to the degree possible, determined.

As stated before, protocol practice will increase.

But most importantly, quality of care will not be assumed—it will be insisted upon.

Regulation of institutional quality. Similarly, there will be insistence on and great efforts to assure the quality of institutions. The Joint Commission for Accreditation of Hospitals will be functioning far more effectively than they have in the past. In essence, they will be performing delegated governmental functions. At best, they will be one step ahead of the sheriff—represented by both governmental and public insistence on high quality. They will not be the friendly, good old boys they were prior to the seventies, or they will not exist at all.

Nursing homes will be subjected to the same regulations and standards as hospitals.

In addition to government, collective purchasers of services will be having their say—at least intermittently.

Personnel licensure. While relicensure of physicians based both on cognitive examinations and audit of practice appears to be a near certainty, the licensure and certification of other health professionals will have undergone severe scrutiny by 1985-1990.

This will have occurred primarily as a response to facts pointed out recently by Dr. Leonard Cronkhite, President of Boston's Children's Hospital Medical Center, namely, that, "there are now 157 identifiable paramedical semi-professionals that the health manpower bureau formally recognizes," and that "each guild insists that each hospital have one or more of their personnel—and they get legislative bodies to require that this be done."

The present moratorium on licensing will continue for sometime.

The re-examination of this question will lead, I believe, to greater institutional responsibility for quality of care and fewer legal requirements for certification and licensing of personnel.

Regulation of health professions education. A friend told me recently that if you give a man *only* a hammer, the whole world looks like a nail to him.

This principle has resulted in some regulation of post-graduate medical education. There will be more and by 1985 not all physicians will be able, as they have for three decades, to choose the specialty of his or her choice. Limited access to medical school will continue. Limited access to post-graduate programs will have just begun.

In sum, during the next decade there will be a broad experimentation with regulation of health care by government, and also efforts within and without government to reinstitute the effectiveness of our traditional and most effective regulator of goods and supplies, the market place.

I have indicated that I do not see the total dominance of regulation or the total re-establishment of the market during the next ten or more years. I believe there are good reasons to anticipate a mix of these two forces, with all of its threats of conflict and counterproductivity. One reason is that health care is not an ordinary commodity, the production and consumption of which can be left to the consumer's choice and ability to pay.

However, because of a limitation of resources, *all* health care cannot be made a basic human right.

This combination of factors leaves us the problem of choosing among unacceptable alternatives.

Where will we come down? I agree with the conclusion that the guarantee of "basic health care" is responsibility of the State. But I am firmly convinced that the direct provision of health care services should not be a function of the State. Only the fulfillment of the guarantee should be a State function. Therefore, we will continue to struggle to define basic health care (it will vary from time to time), and to most efficiently and effectively deliver these health services.

Finally, I will plead once again for physician understanding and participation. Rosemary Stevens wrote in a recent article of, "the intrinsic and continuing political ignorance of American doctors about the processes of change in medicine and society; the average physician's lack of awareness of the broad sweep of social history or even the history of medicine; and the need for psychologic adaptation by practitioners to changes in the next decades."

You are trying to change this assessment. I hope I have been of some help.

Behavior Modification: Perspective on a Current Issue

Bertram S. Brown, M.D.

Behavior modification, one of the youngest and most potent of the modern approaches to treating mental illness and enhancing human functioning, has been caught in a swirl of controversy for most of its adult life.

Based on the general principle that people are influenced by the consequences of their behavior, the principles and practice of behavior modification are founded on more than 75 years of research in experimental psychology. Yet within the past several decades, as behavior modification procedures have become used more and more widely, many different concerns have been expressed.

The public, as well as many mental health professionals, have questioned whether behavior modification procedures are sufficiently well demonstrated through research to be disseminated widely.

This article is based on a recent National Institute of Mental Health publication, *Behavior Modification—Perspective on a Current Issue*, by Bertram S. Brown, M.D., Director, NIMH; Louis A. Wienckowski, Ph.D., Director, NIMH Division of Extramural Research Programs, currently on a year's assignment with the World Health Organization in Geneva, Switzerland; and Stephanie B. Stolz, Ph.D., Chief of the NIMH Small Grants Section, Division of Extramural Research Programs.

Ironically, much of the criticism is directed at what behavior modification is not, rather than what it is. Imprecise and incorrect usage of the term, both by professionals in the field and by the media, has incorrectly linked behavior modification with techniques such as psychosurgery, chemotherapy, and electroshock. In the public eye, it may often be viewed as a one-way means of coercion and control.

On the other hand, behavior modification techniques are gaining increasing stature among mental health professionals. A recent Task Force of the American Psychiatric Association concluded that "behavior therapy and behavioral principles employed in the analysis of clinical phenomena have reached a stage of development where they now unquestionably have much to offer informed clinicians

in the service of modern clinical and social psychiatry."¹

Because of these widely divergent views, and also because the techniques of behavior modification can be effectively used by informed persons outside the mental health field, an understanding of the history, the basic procedures, and the ethical issues associated with behavior modification is useful to the medical practitioner.

An Historical Overview

In the introductory lines of his widely read *Beyond Freedom and Dignity*, behaviorist B.F. Skinner wrote, "In trying to solve the terrifying problems that face us in the world today, we naturally turn to the things we do best. We play from strength, and our strength is science and technology."²

It is this line of reasoning that has induced behavioral scientists to devise ways of systematizing the attempts people have made throughout history to control their environment and to find better ways of acquiring new skills and capabilities. Large scale social applications of technology to behavior remain untested to a great extent, however, and only within the past 15 to 20 years have direct clinical applications of behavioral research come into widespread use.

Though the clinical uses are relatively recent, the basic experimental work designed to obtain a precise understanding of the principles of learning dates back to the 1897 publication of Ivan Pavlov's volume, *Work on the Digestive Tract*, which set forth the principles of the conditioned reflex. Subsequent extensive research in the Soviet Union and in this country notably by E.L. Thorndike, provided the necessary scientific underpinnings to the development of approaches to monitor and modify interactions between an organism and its environment.

Sporadic reports of efforts to apply the new knowledge to such clinical problems as enuresis in children appeared in the literature in the 1920's and 1930's. But much of the impetus for the surge of clinical applications that began in the late 1950's and continues to gain momentum today originated in three major laboratories in the decade following the war. South African psychologist Joseph Wolpe and his colleagues sought direct clinical applications for the research of Pavlov and his contemporaries and successfully introduced several keystone techniques, such as "systematic desensitization," an anxiety reduction procedure widely used today.

At London's Maudsley Hospital in the 1950's, investigators led by H.J. Eysenck were emphasizing the

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learning theory aspects of behavioral principles. The London group supported Wolpe and stimulated creative clinical research instrumental in closing the gap between laboratory-based learning theory and psychotherapeutic practice.

The major concurrent American contribution was the research on operant conditioning conducted by Skinner and his colleagues at Harvard. Focusing on individuals' behavior, the operant conditioners moved quickly from general theory and stressed behavior modification as an approach to treatment of specific problems. The subsequent spread of behavioral therapies was rapid, for on the whole, applied researchers and clinicians found that principles developed in the laboratory could be applied effectively to many problems in the real world.

What is Behavior Modification?

Behavior modification today is a family of techniques that have in common the goal of improving persons' lives by helping to alter specific aspects of behavior. But to understand behavior modification *per se*, it is necessary to clarify its relationship to a broader concept, behavior influence.

Behavior influence occurs whenever one person exerts some degree of control over another. This is constantly evident in such diverse situations as formal school education, advertising, child rearing, political campaigning, and other normal interpersonal interactions.

Behavior modification is a special form of behavior influence derived from laboratory research such as that cited above. Behavior modification emphasizes systematic monitoring and evaluation of the effectiveness of the application of basic learning principles.

Behavior therapy is a term sometimes used synonymously with behavior modification. It refers mainly to clinical interventions, usually applied in a one-to-one, therapist-patient relationship.

With these brief definitions in mind, it may be useful to consider several misconceptions about behavior modification. It is not a therapeutic approach amenable to the resolution of existential crises. Operating on the belief that people are influenced by the consequences of their behavior, the therapist views the current environment as most relevant to determining behavior, rather than early life experiences, enduring intrapsychic conflicts, or personality structure. Nor are behavior modification techniques merely "commonsense." Though most behavioral approaches are not esoteric, their proper use requires rigorous organization of often contradictory commonsense notions.

Perhaps most importantly, behavior modification techniques do not encompass techniques such as psychosurgery, electroshock, or chemotherapy, so often

portrayed under the rubric of behavior modification in the public media. Only under specific circumstances are drugs such as Anectine, or emetics such as Antabuse, used as aversive control measures in behavioral treatment of, for example, alcoholism. Their administration independent of a specific, targeted behavior of a patient is inappropriate to behavior modification.

The Practice of Behavior Modification

In the professional use of behavior modification, a contractual agreement may be negotiated by the client and therapist, specifying mutually agreeable goals and procedures. When the program is to benefit a mentally disadvantaged group such as the retarded, senile, or psychotic, contractual responsibilities may rest with the individuals' legal guardians. Who the appropriate person is to make a contractual agreement for a prisoner remains a complex and unsettled issue, one that merits separate consideration.

Through the course of a behavior modification program, the service recipient or his representative should be kept fully informed of the results of the treatment as it progresses, and also participate in any revision of goals or techniques.

The initial analysis of the problem typically should begin with a detailed description of the distressful or target behavior. The descriptions should be based on observations of the individual and may be careful quantitative records or statements about the relative frequency of various behaviors. The observer may be the therapist or his agent, a peer of the individual receiving treatment, or the individual himself.

With an understanding of the problem, the behavioral goals are to be viewed in the context of everything the person is able to do to attain them, and also in terms of the kinds of support his usual environment is capable of providing over the long term.

Behavior modification, then, involves the systematic variation of behavioral and environmental factors thought to be associated with an individual's difficulties, with the primary goal of modifying his behavior in the direction that he, in conjunction with his agent and therapist, has chosen. Some specific behavior modification techniques are described briefly below.

Positive reinforcement is a technical term roughly synonymous with reward. A positive reinforcer is any event following a given response that increases the chances of that response recurring. Typical positive reinforcers included tangible items such as money or tokens, social actions such as praise or attention, and activities such as the opportunity to participate in recreation. In general, positive reinforcement is used to develop and maintain new behavior.

Aversive controls are occasionally used to combat some types of inappropriate behavior such as addictions and sexual deviances. There are several methods

of application of aversive controls. Perhaps the most commonly used is brief, low level electric shock, particularly effective in the elimination of self-injurious behavior. Shock used in this context is entirely different from electroconvulsive therapy. Another form of aversive control might be the removal of earned positive reinforcers. It is essential, particularly in dealing with institutionalized populations, that appropriate safeguards for the rights and dignity of patients be included in programs entailing aversive control techniques.

Overcorrection is a behavior modification technique combining positive reinforcement and aversive control that is used to discourage inappropriate behavior. In this procedure, the person who has engaged in disruptive activities not only remedies the situation he has caused, but also "overcorrects" it. For example, a patient who, in a fit of rage, messes his living quarters may be required to straighten not only his own quarters but those of other patients as well.

Systematic desensitization involves gradual, progressive exposure to feared situations. The patient is taught to relax (perhaps with the temporary aid of a drug) and then to imagine or encounter increasingly anxiety-evoking situations. The technique has proved particularly effective in dealing with phobias.

Ethical Issues and Safeguards

Various ethical concerns, which essentially are the common property of all medical and psychiatric practitioners, have been alluded to throughout this discussion. However, special characteristics of behavioral approaches, such as the diversity of patients, programs, and settings, add a measure of complexity to ethical issues and warrant separate discussion.

With a clientele that ranges from the normally functioning adult outpatient, to the institutionalized client, to students, to prisoners, the question of client involvement and informed consent requires careful review by behavioral therapists.

Informed consent requires, on the part of the therapist, an understandable description of what will be involved during the course of a treatment program, an assessment of the client or patient's ability to understand and judge the merits of the treatment proposal, and an evaluation of the extent to which consent is truly voluntary.

Because of the disparity among clients and settings, any "universal" standard setting has proved difficult. Each of the major professional organizations, as well as the DHEW, has established ethical guidelines and standards. Nonetheless, members of review groups must be sensitive to subtle issues, such as the identity of the true client—i.e., the institution for whom they review, or the institutionalized individual?—and the objectives of the "front line" treatment agents.

Effectiveness and accountability are key elements of ethical responsibility. Careful monitoring is required to ensure that goals agreed on by all appropriately involved parties are being achieved. If they are not, the therapist may find it necessary to revise the procedures, but only with the knowledge and approval of the client or client's representative.

An additional ethical issue specific to behavior modification is raised because many techniques can be used by paraprofessionals or other persons who may lack the training to evaluate a therapy program. When such persons are involved in the delivery of treatment, responsibility should be delegated so all facets of a program are designed, monitored, and evaluated by trained professionals.

Emerging Legal Rulings: Implications for Behavior Modification

Despite, or perhaps inspired by the increasing concern over the ethical issues involved in the treatment of mental illness, the courts in recent years have played an increasingly significant role that may prove to have a major impact on the entire field of behavior modification, as well as other psychological therapies. Because recent rulings extend rights that are considered basic, they must presumably be available to all persons, regardless of institutional or legal status.

With respect to the institutionalized patient, judicial rulings are not necessary to emphasize that aversive techniques are unacceptable when they are used solely for oppressive purposes or without the informed consent of the patient or his guardian. On the contrary, recent legal reinterpretations relating to human welfare have been concerned mainly with limiting possible abuses of positive reinforcement.

For example, the placement of hospitalized patients in on- and off-ward jobs has long been justified on the grounds that such opportunities provide patients with useful vocational skills for post-discharge employment. Incorporated into various behavioral programs, such jobs also have enabled patients to earn positive reinforcement "credits" or privileges. Yet the decision in *Wyatt v. Stickney*,³ in which the court barred all involuntary work by mentally handicapped patients on hospital operations and maintenance, specifically stating that patients' privileges should not be contingent on such work, has restricted the use of hospital work as a source of positive reinforcement.

Here, the court specified jobs that could be done by patients and held that patients must be compensated for that work at the prevailing minimum wage.

Under the *Wyatt* decision, apparently the only types of work exempt from minimum wage coverage are therapeutic work unrelated to hospital functioning and tasks of a personal housekeeping nature.

The effect of this and other rulings—e.g., *Souder v. Brennan*,⁴ that extended the minimum wage ruling to all persons institutionalized in non-Federal facilities for the mentally ill and mentally retarded—that have defined as basic rights many of the items and activities that until now have been employed as reinforcers in token economies will be to induce the development of new types of positive reinforcers.

Other legal rulings that have touched on the issue of “right to treatment,” though inconsistent to date, might encompass restrictions on the use of some behavior modification techniques. At the same time, a court-ruled “right to effective treatment” might result in a requirement that all therapies include the same type of continual monitoring for effectiveness that is generally standard practice in behavior modification programs.

It is still early to draw fully the clear implications of all the recent rulings in this area. It is certain, however, that the next decade will see the resolution of many remaining questions.

Conclusion

Public debate surely will continue concerning the issues that surround the use of behavior modification techniques. Professional evaluation of these techniques and public discussion of them can help prevent abuses in the use of behavior modification procedures, as well as foster public understanding and acceptance of beneficial procedures. Psychologist Perry London, writing in the *American Psychological Association Monitor*, noted that “. . . a decent society

regulates all technology that is powerful enough to affect the general welfare, at once restricting the technicians as little as possible and as much as necessary.”⁵ In that context, both continued monitoring of behavior modification by the public and further research on this important technology are needed to serve society and the individuals who make it up.

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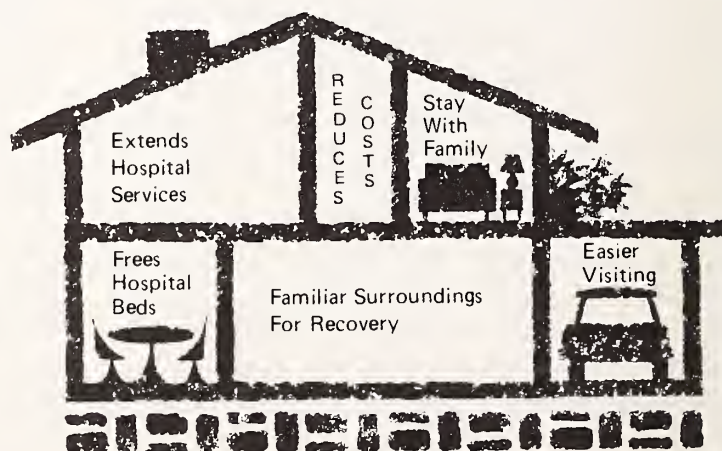
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Irwin H. Lepow, M.D., Editor

Primary Biliary Cirrhosis

Joel B. Levine, M.D.

Case Presentation

The patient is a 56-year-old white female who presented initially, at age 44, with complaints of pruritus and fatigue. She was in good health until 4 months prior to evaluation when intractable itching unresponsive to topical therapy developed. Two weeks prior to admission scleral icterus and dark urine were noted. She denied abdominal pain, fever, or weight loss. Past history had been negative for known hepatobiliary disease, drug or toxin exposure or previous episodes of pruritus especially during pregnancy. On initial examination xanthelesma, tuberous xanthoma, and dermal hyperpigmentation were noted. The liver was enlarged (17 cm) but the spleen and gallbladder were not palpable. Pertinent laboratory data included an elevated serum bilirubin (6.7mg%, direct 5.0mg%), a 5 times elevation of the serum alkaline phosphate and a normal serum SGOT. Serum cholesterol was 844mg% (normal < 250mg%).

The patient underwent laparotomy for diagnostic evaluation of the liver and biliary tree. The gallbladder and common bile duct were normal but wedge biopsy of the liver was interpreted as diagnostic of primary biliary cirrhosis.

Through inquiry and self education, the patient became aware of the expected natural history of her illness. Yet for the next 10 years she remained generally well and was gainfully employed. Pruritus was episodic but responsive to cholestyramine (Questran). Greasy stools, bone pain, and occasional epistaxis developed. Periodic physical examination still revealed hepatomegaly, xanthelesma, and tendon xanthoma. Steatorrhea was documented and low fat diet and eventually medium chain triglycerides were prescribed. Supplements of calcium, magnesium, vitamin D and other fat soluble vitamins were employed.

In 1976, she was readmitted for complaints of hematemesis and melena occurring one day before admission. Gastroscopy and contrast studies confirmed esophageal varices but no active bleeding site was observed. Physical examination revealed jaundice and hepatosplenomegaly but xanthomatosis was no longer evident. Laboratory studies showed a marked decrease in both alkaline phosphatase and cholesterol but the serum bilirubin remained elevated at greater than 10mg%. In hospital, bleeding did not resume and she continues to do well on an outpatient basis.

Discussion of Case

Dr. Joel B. Levine: This discussion should remind us that each generation of gastroenterologists is newly challenged by light of current knowledge to reexamine the relationships between recognizable clinical syndromes and their characteristic pathology. In the late 1930s, Thannhauser, a student of lipid disease, introduced the term, "Xanthomatous Biliary Cirrho-

sis," in order to designate a histologic pattern of xanthoma cells and bile duct fibrosis as specific for a long appreciated clinical disorder affecting middle aged women.¹ The syndrome, fully described by Addison and Gull in 1851, was characterized by the presence of xanthomas, pruritus, hepatomegaly and hyperpigmentation.² Though he initially viewed the hepatic changes as the consequence of a primary defect in fat metabolism, he continued his analysis with appealing objectivity and admirable logic. By subsequently obtaining specimens from patients showing only the earliest indications of the clinical disorder, he observed a previously unrecognized pattern of bile duct inflammation. This distinct small bile duct injury was to prove to be premonitory to the later cirrhotic changes he had described in patients with the more advanced clinical syndrome. Thannhauser now hypothesized that this bile duct lesion preceded the more clinically obvious accumulations of cholesterol. With this refocusing, it was but a few years before Ahrens coalesced the clinical and pathologic correlation into the term, Primary Biliary Cirrhosis (PBC).³

Clinical Presentation and Diagnosis

Primary Biliary Cirrhosis is predominately a disorder of women with a female:male ratio of 8:1 and a clustering of cases in the 4-6th decades. Yet new insights and methods have permitted both earlier diagnosis and recognition of possible *forme fruste* patterns of illness. For example, the diagnosis may now be sought for and confirmed in a younger woman presenting with protracted pruritus of the third trimester of pregnancy.⁴ Indeed, the majority of patients will present with pruritus antedating by months or years the onset of jaundice. This pattern remains a reliable but not the sole clinical presentation.⁵ (Table 1) In 20%, icterus may never develop leaving it for the wary dermatologist, consulted for intractable itching, to consider the diagnosis. Conversely, jaundice and pruritus may be concurrent so that the general surgeon may uncover several cases in the course of evaluating middle-aged women for patency of the extra hepatic biliary tree. Less commonly seen are presentations of nonspecific fatigue, weakness and weight loss, isolated hepatomegaly or silent stigmata of portal hypertension. With the increased use of Auto

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Presented in Farmington on August 4, 1976.

Table I
CLINICAL PRESENTATION OF PRIMARY BILIARY CIRRHOSIS 100 CASES *

Presentation	No.
Pruritus	57
No subsequent icterus	16
Jaundice within six months	14
More than six months	27
Pruritus and Jaundice	20
Jaundice preceding pruritus	2
Jaundice only	6
Fatigue, weakness, weight loss	10
Hepatosplenomegaly	3
Portal hypertension	4
Abnormal laboratory tests	4
Other diseases	4

*From Sherlock

Analysers screening, cases are being detected by revealing in asymptomatic patients marked elevations of the serum alkaline phosphatase.

PBC may be seen in association with a variety of autoimmune disorders (Table II). There are data

TABLE II

ASSOCIATED DISEASES
1. SJOGREN'S DISEASE - SICCA SYNDROME
2. SCLERODERMA - CRST
3. RHEUMATOID ARTHRITIS
4. AUTOIMMUNE THYROIDITIS
5. ULCERATIVE COLITIS
6. LUPUS ERYTHEMATOSUS
7. RENAL TUBULAR ACIDOSIS

suggesting that the Sicca syndrome, with or without arthritis, may be observed in nearly ¾ of PBC patients.⁶ These relationships thus not only constitute a mode of presentation but imply that PBC may relate to a broader context of multisystem immune disorders.

As suggested, a key biochemical hallmark of the early stages of PBC is the substantial elevation of the serum alkaline phosphatase occurring with either subclinical or minor increases in serum bilirubin. Considerable skepticism should be encouraged in accepting a normal alkaline phosphatase as being consistent with the diagnosis. Deep jaundice, which may appear later in the course of the disease, is in fact an uncommon presenting sign. High serum lipid levels are usual and may antedate the clinical appearance of xanthelesma and xanthoma. Eventually a decline in serum alkaline phosphatase and cholesterol may

herald incipient liver failure. Measurement of the fasting and post prandial serum bile acids may become an even more sensitive parameter for the assessment of disease progression.⁷

A variety of immune markers may also serve an adjunctive role in establishing the diagnosis of PBC. An elevated IgM though by itself nonspecific may in concert with the high alkaline phosphatase be strongly suggestive. Most attention, however, has been given to the detection of a serum antibody (AMA) directed against the inner membranes of mitochondria. A summary of the incidence of a (+) AMA in PBC, as compared to other liver diseases, is presented in Table III.⁸ The AMA is an early appearing and

TABLE III

RESULTS OF TESTS FOR MITOCHONDRIAL ANTIBODY*	
DIAGNOSIS	POSITIVE TESTS/TOTAL NUMBER OF PATIENTS (% POSITIVE)
PRIMARY BILIARY CIRRHOSIS	158/188 (84)
CHRONIC ACTIVE HEPATITIS	8/77 (11)
CRYPTOGENIC CIRRHOSIS	2/33 (6)
OTHER FORMS OF CIRRHOSIS	0/244
VIRAL HEPATITIS	0/332
DRUG-INDUCED HEPATITIS	3/73 (4)
OTHER FORMS OF HEPATITIS	0/87
EXTRAHEPATIC BILIARY OBSTRUCTION	4/180 (2)
NONOBSTRUCTIVE BILIARY TRACT DISEASE	0/66
HEPATIC MALIGNANCY	0/124
MISCELLANEOUS HEPATIC LESIONS	2/230 (1)
COLLAGEN DISEASES	1/62 (2)

*THE SERUMS OF 1696 PATIENTS WERE TESTED.
FROM KLATSKIN

persistent marker but being neither tissue nor species specific is unlikely to play a pathogenetic role in PBC. Its titer is unrelated to the duration of symptoms or to the presence of cirrhosis. Finding the AMA is particularly helpful in those patients having a compatible pathology but with such atypical clinical or laboratory features as the absence of pruritus or a normal serum cholesterol. Its greatest utility may be that despite its limitations and lack of absolute specificity, PBC is statistically unlikely in its absence.

Establishing the patency of the biliary tree continues to be an obligatory task during an evaluation for PBC. New techniques: computerized tomography, ultrasound, skinny needle and endoscopic cholangiography have allowed for improved non-surgical analysis. The role of surgery is further redefined by a recent ERCP study, in PBC patients, revealing a greater than 30% incidence of co-existent calculus biliary tract disease.⁹ Thus, Klatzkin has suggested that laparotomy still be selectively performed on those PBC patients with radiologically documented cholelithiasis, unexplained fever, significant epigastric pain, or a sudden rapid increase in jaundice.⁸

Despite considerable investigative efforts into the immunology of PBC, it is unclear if the serologic markers associated with the disease are of primary importance or merely reflective of an injury response to viral, toxic, or other, as yet undefined agents. Tests of humoral immunity have demonstrated a decreased antibody response to haemocyanin. Measurements of cell mediated immunity have shown decreased lymphocyte transformation to different mitogens and decreased leukocyte migration in the presence of "liver specific" antigen.¹⁰ Despite these intimations of impaired immune responsiveness, the absolute number of immunocytes, whether B cells, active rosette forming cells, or "null" cells does not appear to be diminished.¹¹ Recently, a serum antibody directed against bile canaliculi has been demonstrated.¹² Its detection in less than 50% of PBC patients casts doubt as to the primacy of its role.

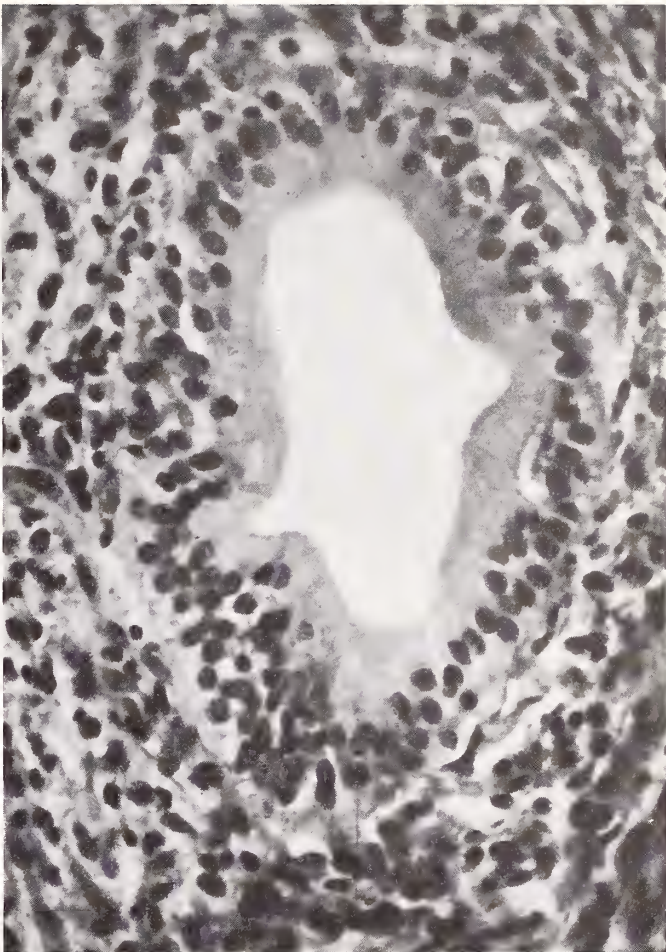
Finally, a genetic predisposition is supported by data reflecting an increased incidence of seroimmunologic abnormality in relatives of patients with PBC. Such data include 40% of relatives with an increase in immunoglobulin levels, 7% with a positive AMA and recent reports of PBC occurring among siblings.^{13,14}

Pathology

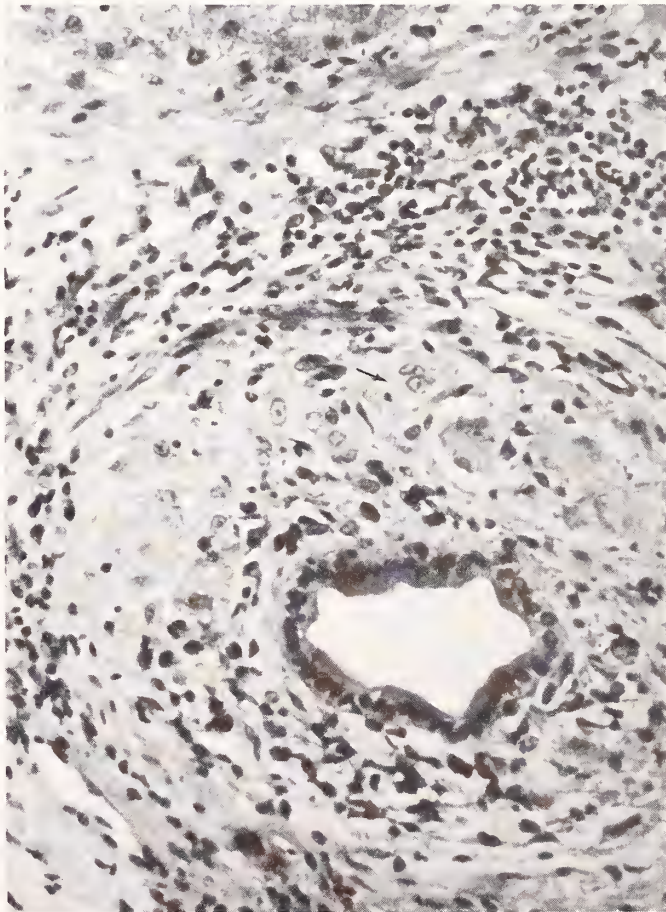
The pathology of PBC has been divided, mostly for didactic purposes, into stages reflecting an evolution from an initial inflammatory bile duct lesion to an established cirrhosis marked by bile duct depletion. The first stage is referred to as the "florid duct" lesion and is considered, by Sherlock, as pathognomonic for the disorder.⁵ Its hallmark is inflammatory injury to the epithelium of larger interlobular and septal bile ducts. The type of injury ranges from epithelial cell vacuolization and stratification of basal nuclei to frank rupture. A dense lymphocyte and plasma cell infiltrate is seen around the damaged duct, and peri-ductal granulomas are often evident. In this early lesion, the periportal limiting plate remains intact and only minimal cholestasis is evident (Figure 1).

As inflammation destroys the larger ducts, smaller bile ductules proliferate creating a lesion more widespread throughout the expanded portal tract but less specific. These ductules are atypical in that they may lack a lumen, are located at the periphery of the portal tract, and are unaccompanied by hepatic arterioles or portal venules. Moderate peri-portal limiting plate necrosis, peripheral cholestasis, and Mallory's Hyaline are frequently observed.

With disease progression even these proliferating ductules are destroyed and irregular stellate scars and eventually regenerating nodules, devoid of ductal or ductular elements, appear. Thus the appearance of a cirrhosis with striking peripheral cholestasis but with



a



b

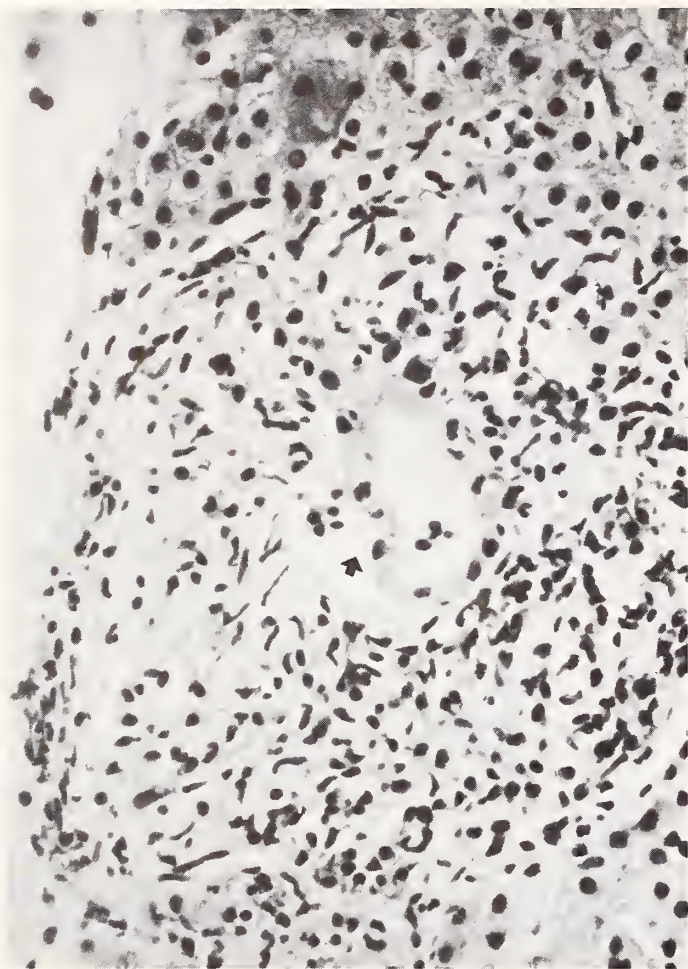


Figure 1

Progressive injury to a septal bile duct in early Primary Biliary Cirrhosis Fig. 1a, b, c: 1a) Stratification of basal nuclei; 1 b) granuloma formation (arrow) in thickened and infiltrated wall; 1 c) inflammatory reaction surrounding area of duct rupture (arrow).

a paucity of bile ducts is most suggestive of the later stages of PBC.

It is important to emphasize that the pathognomonic florid duct lesion is seen in less than $\frac{1}{3}$ of needle biopsy specimens as compared to $\frac{2}{3}$ of the larger surgical wedge biopsies. Closed needle biopsy more frequently yields a "compatible" histology containing proliferating ductules, but absent ducts, lymphoid aggregates and peripheral cholestasis. These "compatible" findings, in conjunction with the AMA and a suggestive clinical and laboratory profile can, with substantial accuracy, support the diagnosis of PBC.

Differential Diagnosis

Resolving the differential diagnosis has been made somewhat easier by our expanded serologic and radiographic data base. Precirrhotic, active bile duct destruction followed by a reduction in the number of interlobular bile ducts are the most specific lesions. In secondary biliary cirrhosis due to long standing extrahepatic obstruction, periductal fibrosis is more

prominent than duct disruption. In addition bile lakes and bile infarcts, features almost never found on the lobule periphery in PBC, are evident. A (+)AMA has been reported in cases of malignant extrahepatic obstruction making ERCP and skinny needle cholangiography especially useful techniques.¹⁵ Duct injury is generally absent and cholestasis central in both Sclerosing Cholangitis and the pericholangitis associated with inflammatory bowel disease. By needle biopsy alone, with its decreased chance of yielding the florid duct lesion, distinction from Hodgkins Disease and protracted drug-induced cholestasis may be difficult. Here, the clinical setting and the AMA then accrue an even greater diagnostic value.

Yet to the consternation of gastroenterologists, overlap cases with both chronic active hepatitis (CAH) and cryptogenic cirrhosis exist and perplex. Biopsies of a fully established cirrhosis containing lymphoid aggregates and even early bile duct destruction may occur in patients lacking any signs, symptoms, or laboratory features suggesting PBC.¹⁶

There is also increasing recognition of those grey zone patients in whom the clinical course strongly suggests CAH but whose pathology resembles PBC. Reliance upon the Hepatitis B Surface Antigen (HBsAg) or the AMA cannot be absolute, as crossover exists. The Mayo Clinic, taking advantage of the disparate response of the two diseases to steroids, has suggested a short term prednisone trial.¹⁷ Their data concludes that CAH will respond, clinically and pathologically, whereas PBC will demonstrate no significant improvement.

PBC has been traditionally viewed as a remorseless fatal illness of relatively short (< 5 years) duration. Though death from liver failure or the complications of portal hypertension is still the expected outcome, early diagnosis of the minimally symptomatic patient has demonstrated that the duration of disease may approach 15 years and that patients may have a protracted period of relative stability.

Therapy

The therapy of PBC remains empiric with regard to the symptoms and consequence of cholestasis and controversial with regard to the amelioration of the underlying problem. Hypercholesterolemia and steatorrhea are improved with substitution of medium chain for long chain dietary fats. Osteomalacia is minimized with calcium and vitamin D supplements. Present emphasis on studies of intrahepatic vitamin D metabolism in varieties of liver disease will likely lead to improved therapy of the often severe bone demineralization. Pruritus is principally treated with the bile salt sequestering resin, cholestyramine, but at the eventual sacrifice of increased steatorrhea.

Clinical experience has demonstrated the inability of steroid therapy to either improve survival or decrease the incidence of cirrhosis. These conclusions, coupled with steroid induced osteopenic side effects, have contraindicated their use in PBC. Their role as an aid in helping to identify cases overlapping with chronic active hepatitis has been discussed.

An immunosuppressive agent, Azothiaprime, has also undergone a prolonged therapeutic trial.¹⁸ Though there was short term improvement in the alkaline phosphatase and a decrease in periductal inflammation, long term survival was not statistically improved.

Recently, interest has focused on the finding of an increased hepatic copper content in PBC.¹⁹ The levels observed have been in a range seen in Wilson's Disease and prolonged extrahepatic obstruction. Significantly, other forms of cirrhosis, notably alcoholic, appear to have a markedly lower liver copper. Though the premise that increased hepatic copper promotes or accelerates inflammation and fibrosis is still speculative, several studies are now underway utilizing the copper depleting agent, penicillamine.

The evolution of our understanding of PBC as a concept and in today's patient should reinforce the merits of close clinical observation, the ability to disbelieve our dogma and the wisdom of heeding the advice of skeptics.

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Alcohol Treatment Services in Connecticut Hospitals

J. Kevin Kinsella, Ed.D., M.P.H.

Introduction

According to the latest studies from authoritative governmental and academic sources, alcoholism is one of the nation's leading public health problems. Estimates of the number of alcoholics in the United States range as high as nine million, with the financial loss attributable to the effects of alcoholism estimated as high as \$25 billion yearly.¹ The acute general care hospital is one of the institutions in society which should serve as a necessary and vital resource in the overall care-giving system for individuals affected by this far-reaching problem. Over the years, however, the role assumed by the acute general care hospital has been limited to the diagnosis and management of the medical complications of alcoholism.² With the advent of changing social attitudes toward alcoholism, and legislation which redirects responsibility for this problem from the criminal justice system to the health care system, has come a recognition on the part of health professionals of the illness model of alcoholism.³ This redefinition has caused acute general care hospitals to reexamine and, in many cases, expand their role to include a more complete range of services for the care and rehabilitation of the alcoholic.

Hospital personnel in all areas of the country are being asked to participate in the planning and development of alcohol consortia or community service networks; serve on alcohol advisory boards; initiate day treatment and detoxification programs; and expand hospital involvement in aftercare systems. For the most part, those charged with the responsibility of charting the hospital's course have had little training or educational exposure in the field of alcoholism. This unfamiliarity often results in the hospital engaging in a plan of action which proves to be least effective for hospital, consumer and community.

Recognizing this need for educational assistance in the area of hospitals and alcoholism treatment services, the Connecticut State Alcohol Council and the Connecticut Hospital Association in June, 1974, designed a program for the purpose of providing alcohol training and education activities to Connecticut's thirty-six acute general care hospitals. Administered through the Connecticut Hospital Research and Education Foundation, Inc. (CHREF), the program is in its second year of operation and has made substantial progress toward the achievement of its ultimate goals

of assisting acute general care hospitals in the development of systems for the comprehensive care of the alcoholic patient; aiding in the design and establishment of ongoing educational programs within each institution; and assisting the hospitals to prepare for the decriminalization of public intoxication.

The Program

The CHREF Alcoholism Training Program consists of three main areas of activity: (1) sponsoring ongoing educational seminars on topics and issues related to alcoholism; (2) conducting training programs in hospitals designed to upgrade the skills and techniques of hospital personnel in the clinical care and management of alcoholism and alcohol-related problems and; (3) consulting with hospitals regarding development and/or refinement of standards and practices for treatment and care of the alcoholic patient and the coordination of hospital efforts in these areas with community-based services.

Activity in all three of these areas revolves around the efforts of hospital alcoholism program coordinators. This group is composed of nurses, administrators, physicians and social service personnel who have been appointed by Chief Executive Officers of their respective institutions as the hospital liaison with the CHREF Alcoholism Training Program. The hospital alcohol coordinators meet approximately every five weeks to exchange information and ideas and to participate in panel presentations covering issues of concern ranging from the latest advancement in clinical techniques to the financial management of alcoholism services. The resources and facilities of the Hospital Association are used to enhance and promote this process whenever possible.

Utilizing the framework of hospital alcohol coordinator conferences, staff of the CHREF Alcoholism Training Program work with hospital representatives to conduct regular onsite visits for the purpose of assisting in the planning of educational workshops and other inservice education projects. Visits usually last the better part of a day and include a brief review of the extent of current activity and nature of programs already in existence in the area of alcohol education. Initial meetings are held with administrators, emergency room staff and directors of appropriate services to assess need and elicit suggestions. Educational activity planned and presented thus far has centered on a workshop model designed to accomplish five goals: (1) impart skills and techniques in the treatment of the alcoholic and alcohol-related ill-

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nesses; (2) address issues of attitudes and behavior of hospital staff toward alcoholics and the concept of alcoholism as an illness, and suggest means of approaching the problem; (3) identify and begin to develop a viable "alcoholism team" for each institution composed of representatives of all disciplines and departments relevant to proper management and disposition of alcoholic patients; (4) review the extent and magnitude of the problem on a local level and set a time table for development of a formalized treatment plan for individual institutions and related health care organizations and; (5) provide information and answers to specific hospital personnel questions regarding the medical, legal and practical aspects of hospital care of the alcoholic patient. These workshops are often jointly sponsored by neighboring hospitals that share common service boundaries. Hospital administration demonstrates support by joint sponsorship and by providing released time for staff who participate. Workshop leaders are health professionals who have demonstrated expertise in the treatment of alcoholism and alcohol-related illnesses and are currently working in Connecticut hospitals.

In the process of conducting an educational needs assessment, the basis for the developmental and standard-setting program area is instituted. CHREF staff work with hospital alcohol coordinators to review current standards and practices, including hospital admission policies, detoxification procedures, other treatment programs within the hospital, discharge planning and referral, etc. If hospitals lack programs or policies for alcoholism treatment, staff work with hospital personnel to help develop programs that are best suited for the individual hospital and the community, given available resources and the extent and nature of alcohol-related problems. In other instances, where hospitals have existing programs, CHREF staff can be helpful in providing information on current community and state resources to aid in the more effective coordination of alcohol services. Most important, CHREF staff can advise the hospital as to its responsibility for providing a planned treatment regimen for the alcoholic patient under the mandate of Public Act 74-280 the "Alcoholism and Intoxication Treatment Act" passed by the Connecticut legislature in June, 1974, and scheduled to be implemented in June, 1976.

In addition to these three main areas of activity, the training program is involved in a variety of special projects which contribute to the achievement of overall goals and objectives. In one major Connecticut metropolitan area, CHREF staff conducted a survey in the emergency rooms of all three hospitals to obtain more complete and accurate data on the magnitude of the problem and to assist in state and local

planning efforts. In another urban area, staff are working with a consortium of hospitals and state and local alcohol officials in an attempt to improve the coordination of the existing resources and define new models of care that more adequately address special problems such as chronic recidivism and the lack of special programs and facilities for alcoholic women and Spanish-speaking patients. Conferences for hospital personnel on national accreditation standards and the relationship of the health care system with the criminal justice system have been jointly sponsored with the State Alcohol Council. A close working relationship is maintained with the Connecticut Association of Alcohol Councils, resulting in cooperative efforts in obtaining state and federal funding for acute care facilities and the scheduling of educational programs. The ongoing hospital and health conferences sponsored by the Connecticut Hospital Association are utilized by the CHREF Alcoholism Training Program as forums for the dissemination of information, presentation of programs designed to meet specific needs, and for the exchange of ideas.

Models of Care

Initial program activity has identified and assisted in the development of various models of care for the treatment of alcoholism in the acute general care hospital. These models vary considerably from hospital to hospital and their evolution is due to factors such as community involvement, attitudes of medical and nursing staff, leadership of hospital administration, available facilities, and financial factors which include third party reimbursement, state and federal grants-in-aid and local voluntary contributions. Services for alcoholism and alcohol-related illnesses in Connecticut's thirty-six acute general care hospitals can be categorized according to six service patterns:

(1) *Referral*—This model relies on community, voluntary and public agencies to provide almost all aspects of care and treatment. The hospital views its role as providing initial assessment and evaluation. If the patient has medical complications, including acute alcohol withdrawal syndrome necessitating further diagnosis and care, he is treated on an inpatient basis. If the hospital has a psychiatric unit, admission policies to this unit may exclude alcoholics. In the case of either a medical or psychiatric admission, the patient is neither treated in a particular section specified for alcoholism treatment, nor is he treated by staff designated or trained as alcohol treatment specialists. Treatment of most patients does not go beyond emergency room triage and care. "Holding" in examining rooms is a frequent practice for patients who are intoxicated or incapacitated, and on occasion a brief admission for one to two days is warranted on the

basis of individual social/health conditions. Most often, however, patients who are incapacitated are committed to a state mental health facility. Functionally, this model has as its basis the general principles of emergency room practice: evaluation and management are predicated on a speedy and accurate assessment of the problem, with referral to departments or outside agencies for intermediate and extended care.⁴

(2) *Social Service*—In this model, hospital authorities formalize contacts with local and state voluntary and social service agencies to augment the services of the acute general care hospital. The role of the hospital remains the same as in the referral model, except that the manner in which those services are delivered is markedly improved. The use of an on-call list of volunteers from local Alcoholics Anonymous groups to assist patients during their stay in the emergency room or on a general medical/surgical floor is beneficial in terms of overall care, staff education, and more effective utilization of skilled personnel. Referral practice is promoted by sponsoring weekly or bi-weekly A.A. meetings in the hospital which are open to staff, patients and community.⁵ Workshops and inservice education projects are developed in cooperation with community agencies such as family services, child guidance clinics and alcohol councils. Often work accomplished under this model is coordinated by the hospital's office of social services.

(3) *Educational Awareness*—Building on the models of referral and social services, some hospitals have chosen to establish permanent programs of education and training designed to improve services for the alcoholic patient.⁶ In this model, the hospital employs or reassigns a staff member to spend a majority of his work time as the hospital's "alcohol specialist."⁷ The nature and extent of program goals and objectives are often a direct reflection of the individual priorities of the alcohol specialist. Programs identified to date have chosen to direct resources toward building a strong educational base in the areas of nursing inservice education and medical rounds. The specialist often becomes a case consultant, making visits to referred patients hospitalized under another diagnosis. Although many patients may have multiple admissions due to excessive drinking, hospital nurses and physicians usually only discuss illness in terms of medical complications and not in terms of alcoholism. In this model the alcohol specialist implements hospital policy by discussing with patients their illness, in relation to alcoholism, and by initiating treatment and proper referral.

(4) *Centralized Intake*—Working with community-based detoxification programs, the hospital emergency room provides for all initial intake and evaluation

of individuals with alcohol-related problems. Referral to the emergency room may be initiated by community agencies, family, self or the police. Patients who have medical complications or need acute treatment for detoxification are admitted for inpatient diagnosis and care. Patients with alcohol-related problems who are not in need of hospitalization are released directly to a community sponsored detoxification program. The community detoxification program is closely coordinated with the hospital emergency room by the establishment of medical protocols and program policies.⁸ The role of the hospital is the same as in the three previously mentioned models, with one major difference: initiation of all treatment for the disease of alcoholism and for detoxification begins in the hospital by a formal contract with a community network of services, including the local criminal justice authorities.

(5) *Hospital-Based Detoxification Programs*—In the absence of community-based detoxification programs, some acute general care hospitals have chosen to develop programs which set aside a certain number of beds on general medical/surgical floors for use in detoxification from the effects of alcohol. For the purposes of program definition a distinction should be made between two types of treatment for detoxification: (A) acute and (B) sub-acute.⁹ Acute treatment of the alcoholic patient consists of attention to one or more often related conditions: (1) alcohol intoxication (stupor, coma, respiratory depression); (2) withdrawal syndrome (delirium tremens, convulsions, severe agitation); (3) serious medical complications (G.I. hemorrhaging, hepatic coma, pancreatitis, vitamin deficiency sequelae). Hospitals as a matter of practice have always provided treatment for these acute medical manifestations of alcoholism. (This treatment, however, has rarely been viewed as a special effort in "alcoholism" treatment or even labeled as "detoxification," but instead is considered standard medical practice.) Recently, some acute general care hospitals have chosen to isolate and/or identify beds in a certain section of the hospital staffed by personnel identified as alcohol treatment specialists to treat individuals requiring acute care. In some cases patients requiring subacute care are included on such a hospital service. The patient who is appropriate for sub-acute treatment has only mild to moderate central nervous system depression, tremens without convulsions, and medical complications of a minor nature. Such a patient carries an initial diagnosis of impending delirium tremens or has a past history of excessive drinking which often is managed by "holding for observation" in the emergency room. More recently it has been common practice to release such patients to a community detoxification facility.

Treatment for the medical complications of alcoholism requires extended periods of hospitalization. Three to five days is the common length of stay for patients requiring acute or subacute treatment for detoxification regardless of the treatment setting.

(6) *Alcoholism Treatment Units*—A comprehensive range of services is provided for the alcohol patient in the model of a designated alcoholism treatment unit.¹⁰ This unit, distinguished from other hospital departments by title and location, provides for intake and evaluation, detoxification, an intensive alcohol therapy program with outpatient referral and follow-up and in some instances includes a day treatment modality.¹¹ The length of the programs vary, but ranges from 10 to 30 days; staff is comprised of a variety of professional and paraprofessional personnel. Such units are often originated by expansion of hospital psychiatric units or in some cases are developed from medical detoxification units on medical/surgical services. These units are expected to meet minimum Joint Commission on Accreditation of Hospitals guidelines of at least 12 beds for detoxification and 200 admissions per year, and eventually fulfill all standards necessary for formal alcoholism program accreditation.¹² Alcoholism treatment units combine aspects of traditional hospital based psychiatry and the most successful methods developed by Alcoholics Anonymous.

Discussion

The six groupings used to describe existing models of alcoholism service delivery for patients in Connecticut hospitals should not be viewed as fixed prototypes. When working with the acute general care hospital, CHREF staff urge the development of programs which make the most sense for the individual institution, given the many external and internal constraints, and yet provide the best possible service to individuals suffering from alcoholism and alcohol-related problems. Hospitals often piece together parts of various existing programs which they think most worthwhile in shaping a program of their own.

This process of program development is usually accomplished by visiting and reviewing other hospitals and discussing advantages and disadvantages of models of care. Of the six models presented, each has obvious benefits as well as shortcomings. The referral model is used most frequently because it requires the least expenditure of energy and funds. While meeting the letter of the law, it does little in the way of approaching the spirit and intent of legislation which was intended to allow the alcoholic patient full access to the health care system. The social service model is most effective in hospitals with strong departments of social service or social work. For hospitals with small

or non-existent social service departments, one might speculate that the development of an alcoholism program along these lines could serve to stimulate the hospital's interest in creating more effective and formal ties with voluntary nonprofit community agencies. The education and awareness model provides the distinct advantage of placing responsibility and alcoholism treatment activity on the position of an alcohol specialist. The program's results will depend almost entirely on the job performance of this individual. If the performance is poor, the result can be a virtually non-existent, "paper" program. Even with excellent performance, however, the end result might be a program which is too ambitious, resulting in a situation where the hospital has to respond to unrealistic expectations on the part of its patients and community. Local extensions of the education and awareness model are the development of hospital outpatient services, a strong formalized system of community follow-up and referral, and the possible allocation of space, beds and additional personnel for the creation of a specialized alcohol treatment unit.

Centralized intake as a model has received support from state and federal alcohol officials.¹³ The postulate which is the basis of this model is that alcoholism and alcohol-related problems are medical conditions which require triage and initial treatment within the emergency rooms of acute general care hospitals. Medical care should be no less accessible to the alcoholic than to any other patient; indeed, his alcoholism renders him more susceptible to other acute and chronic illnesses which should be evaluated through the normal routes of entry to the health care system. The disadvantages created by this model, if it is not designed properly, are "clogging" of emergency rooms during certain hours, increased frustration on the part of emergency room staff due to the chronic nature of the illness, and management problems caused by a small minority of disruptive patients.

Hospital based detoxification programs provide immediate benefits in terms of service for the alcohol patient and as a community resource, but in the long run prove to have many disadvantages. As mentioned, acute treatment for detoxification should take place in the acute general care hospital. However, specialization in this area may lead to the automatic admission of many subacute cases which can more effectively be treated in terms of cost and method in the community setting. Isolation of detoxification patients on one hospital service may also not be the most efficient in terms of medical or hospital practice.

Finally, the optimum model of an alcohol treatment unit is only effective for hospitals of a certain size which are located in communities with the proper socioeconomic conditions. Hospitals which have

developed such units are usually above the three hundred and fifty bed level, have a large psychiatric service, and have several key health professionals who have an interest in the field of alcoholism. The major advantage lies in having both an intensive and an intermediate care facility available within the hospital to provide for continuity of care. The major disadvantage is that the service may become exclusive, on the criteria of ability to pay (although third party reimbursement reduces this likelihood) and the probability of successful recovery. While some hospitals with alcohol treatment units have been successful in engaging the community in a process of active participation, others have developed independent of local concerns. In this model program control rests entirely with the hospital. In order to insure hospital and community cooperation, as well as the continuity of care, a structure such as a community advisory board should be included in planning alcohol treatment units.

One approach to the care of the alcoholic not specified above as a model, but certainly noteworthy, is the concept of "open ward management."¹⁴ In this system, hospital and medical staff receive thorough training in all aspects of alcoholism and apply their knowledge on an individual basis regardless of the particular unit or service on which the patient is currently residing. Most individuals with alcohol-related problems are admitted to general medical or surgical floors and as part of the overall system of medical care are treated simultaneously for the medical complications of alcoholism and the actual disease of alcoholism itself. The treatment is not seen as "special" but rather as an extension of basic hospital and medical practice, and, is analogous to open ward management in general hospital psychiatry. This approach differs from the education and awareness model in that the hospital publicly announces its intention of incorporating the treatment of alcoholism into its ongoing service system. Advantages and disadvantages are difficult to assess, for while discussed by several acute general care hospitals, this approach has yet to be developed as a model of care in Connecticut.

Conclusion

Legislative and educational programs in alcoholism are only influential and effective in the development of alcohol services in the acute general care hospital to the extent that they foster a partnership of community and hospital leadership and provide mechanisms which allow for realistic development of services. Alcoholism is a community health problem which re-

quires the attention and resources of all health professionals and concerned organizations and individuals. Hospitals can play a vital role in efforts aimed at addressing the problem; they should not be expected to bear the entire burden of providing services for the non-acute stages of the illness, but they also cannot stand apart from the development of community treatment and prevention programs.

Even under the best of circumstances, hard work and good intentions do not guarantee success in attempting to provide alcoholism services for a community. There must exist proper mechanisms for reimbursement by third party payors as well as financial support from local, state and federal governments. There must be recognition of this responsibility on the part of these official agencies for ensuring adequate program funding. Without such recognition, the very best efforts of hospitals will be inadequate to deal with the problem of alcoholism.

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Healing and the Search for Knowledge: The Physician's Dual Mandate from Society

Thomas Halper, Ph.D.

The other day, I read of experiments suggesting the eventual possibility of inducing bacteria to "manufacture" insulin, pituitary hormones, and other substances now made only by human or animal bodies.¹ Quantities of the substances could be vastly increased, aiding patients and researchers. Even prices would come down.

Taking the conventional utilitarian position, the ethical desirability of these experiments would seem about as unambiguous as it is possible for any human endeavor to be. The potential benefits appear enormous, the costs modest, and the research-related risks to men nil. The search for knowledge in the service of healing is difficult, indeed, to criticize.

Often, however, the matter is not quite so simple. For, in truth, the physician has not one mandate with respect to healing and the search for knowledge, but two. To put it differently, the profession is asked both to heal today and to search for knowledge so that it can heal tomorrow. Given the context of this dualistic mandate, some amount of conflict is unavoidable.

Some Problems: Physician and Patient Perspectives

First, the search for knowledge may be undertaken when the physician recognizes that the subject has no realistic chance to receive a healing benefit. Under this rubric are included some of the most notorious of medical projects: the 430 Alabama black men with syphilis who went untreated from 1932 to 1972 so

that Public Health Service investigators could study the degenerative impact of the disease; and Army experiments with hallucinogenic drugs on 741 unsuspecting military personnel from 1955 to 1967 and surreptitious drug tests by the Central Intelligence Agency, so that the military implications of such drugs could be examined. What is especially distressing in these instances, of course, is that adequate patient consent was never obtained. It was this that permitted the search for knowledge utterly to displace the concern for healing.

Yet it is not difficult to construct cases in which such consent might be given. Perhaps, for example, the patient could be persuaded that the potential societal benefit was great and his discomfort small. Or perhaps he might be convinced that his condition was a hopeless one that might gain some social utility if experimentation were permitted. Absent this consent, there remains a nasty conflict between healing and the search for knowledge.

Second, the search for knowledge may be undertaken when the physician has good reason to believe that the subject might indeed receive a healing benefit. The patient, so the theory goes, becoming properly informed, weighs the possible risks and rewards, and makes his decision to participate accordingly.

One difficulty here lies in estimating the likelihood and nature of the costs and benefits. What are the patient's chances for being helped or hurt? And how will these be manifested, and to what extent? Uncertainty often reduces calculations to guesswork. And even if the probability were fairly well established, aside from the very high risk of serious damage or the very low risk of slight damage, how could a patient determine whether consent was in fact in his best interest? He knows, of course, that even a 1% chance of death may leave him 100% dead. As he tries to decide rationally and prudently, what criteria might be applied to aid him in the agonizing drawing of lines? Must he inevitably fall back on hunches, intuitions, or faith in the authorities?

Third, the search for knowledge may be undertaken when the physician has good reason to believe that there will be no social benefit beyond the mere accumulation of arcane data. Into this category would

THOMAS HALPER, PH.D., Chairman of the Department of Political Science at Baruch College, City University of New York. This paper is based on Professor Halper's presentation at the University of Connecticut Health Center on December 9, 1976, as part of the program, "Focal Issues for the Public and the Professionals—Forum on Human Values and Health Care." The Forums are supported by a grant (CHC-P-7611-G7) awarded by the Connecticut Humanities Council under the auspices of the National Endowment for the Humanities to Stuart F. Spicker, Ph.D., Forum moderator and Director of Humanistic Studies in Medicine in the School of Medicine. The program was co-sponsored by the Capitol Area Health Consortium and Bristol Hospital.

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fall those Nazi doctors' experiments on concentration camp inmates and war prisoners whose purpose was simply to titillate and satisfy the investigators' own sadistic lusts. Inasmuch as medical experimentation would seem to imply a concern for social benefits of a health nature, such so-called "experiments" are perhaps not even deserving of the name.

Fourth, the search for knowledge may be undertaken when the physician has good reason to believe that society might receive a healing benefit at some later date. Last summer, a controversy over precisely this question erupted in Cambridge, Mass., involving Harvard scientists conducting recombinant DNA research, in which portions of DNA molecules from different species are brought together in order to alter the hereditary mechanism of an organism. Investigators talked about the possibility of "gene therapy" and of the laboratory production of vitamins, antibiotics, and hormones, while their opponents argued that the researchers might inadvertently create a strain of cells that might escape their control and inflict a devastating malady upon an unsuspecting—and unconsenting—populace.² In determining whether and under what conditions such research should be permitted to proceed, one, again, must be concerned with probabilities that, again, cannot be accurately estimated. Yet because the consequences of a mistake would be so calamitous, even probability seems by itself a puny consideration. The chances that something might go terribly wrong might be very remote, but that wrong may be so terrible that no imagined benefit would be worth assuming the risk.

Some Problems: Societal Perspectives

Fifth, healing and the search for knowledge, to some extent, must compete with one another for shares of the available health resources. Such resources are necessarily scarce, so that the purchase of one health benefit can, in good measure, be made only at the price of another.

It is, for example, a commonplace complaint that until recently relatively insufficient resources have been directed at job and consumer safety, health education, reversing environmental degradation, nutrition improvement, and so on, while exotic research, underutilized prestigious equipment, lavish facilities, and maldistributed physicians have been consuming great chunks of funds.

With much of this it is difficult to quarrel. If the famous La Londe Report, *A New Perspective on the Health of Canadians*, has one central theme, it is that personal health care is only one factor determining a society's health. Zooming expenditures in this area, therefore, have not affected gross health indices much, nor ought great change to be expected in the

future. This is because health is not merely a function of individual biology, but also of what a La Londe calls "environment," "life style," and "health-care financing and organization." Moreover, there can be no question that self-imposed risks—diet, alcohol and tobacco consumption, and so forth—have profound health implications. Recent UCLA studies, for instance, suggest that seven health-related behavior patterns could increase the life expectancy of a 45 year old male by eleven years.³ The Department of Health, Education and Welfare's annual report to Congress and the President on the nation's health made a similar point. While access to health care has broadened considerably, it said, marked health improvement is blocked by the American life style that includes excessive use of alcohol and tobacco and the lack of proper exercise and diet.⁴

Yet one must always be on his guard against creeping philistinism. To the layman, much of basic research may seem silly, mere scientific makework programs of interest to no one except the researchers. But the flaw may, instead, lie with the layman himself, who is too ignorant to perceive the activity's significance. Or perhaps—as sometimes happens—its significance surprises everyone. It is easy, for example, to imagine politicians ridiculing research on bread mold, and yet from this we did, after all, get the penicillin that has saved many of these same politicians from the ravages of venereal and other diseases. Nor is this familiar example unique. Both of this year's Nobel Laureates in medicine worked in very esoteric areas but acquired very practical information: Baruch S. Blumberg, investigating blood serum in Aborigines, found an antigen that is now routinely tested for in donated blood to prevent hepatitis infection; and D. Carleton Gajdusek, studying a disease found among members of a small cannibalistic tribe in New Guinea, learned about a slow acting virus that may be a cause of such puzzling nervous disorders as multiple sclerosis and Parkinsonism.

But if it has been charged that knowledge has been pursued at the expense of healing, the reverse is also now beginning to be heard. Healing, in other words, is sometimes said to divert resources from research. New York City, for instance, has a hospital system with 5,000 surplus beds (out of a 37,000 bed capacity) and a widespread policy of doing almost anything to keep patients in the hospitals, whether they need to be there or not, in order to get reimbursement from Medicaid, Medicare, Blue Cross, or the patients themselves.⁵ It is hard to deny, say the critics, that a portion of these funds could produce greater health benefits for society, if they were redirected to a search for medical knowledge; and even if they were not so redirected, the current wastage helps to give the whole

health apparatus a reputation for systemic irrationality and cynical greed that may damage the reputations even of the innocent.

(I lay aside here the unrealistic effort to evade the problem of the healing-search for knowledge trade-off by contending that both should receive all the resources they demand. Despite all the rhetoric on society's open-ended commitment to health care, the fact is that health is merely one of the goals we as individuals and as a society pursue. In any case, the health complex is not well situated to complain. From 1965-1975, health expenditures increased 300%, from \$38.9 billion to \$118.5 billion, and could exceed \$250 billion by 1980. Per capita expenditures have increased from less than \$200 in 1965 to \$550 in 1975, and are projected at \$1000 in 1980. As a proportion of the gross national product, health has risen from 5.9% in 1965 to 8.3% in 1975, and is projected at 10% in 1980. Health is now more costly than that old liberal bugaboo, the defense budget.⁶)

Sixth, healing and the search for knowledge may compete for the limited time, energy, and attention of individual physicians. The amount of technical knowledge to be absorbed is great, the time short, the pressure terrific, and the possibility of error frightening. The natural tendency, or so this well-worn argument would have it, is for medical students and young physicians to view their medical role principally as that of scientist or engineer. Since one cannot specialize in everything, to continue, there is an emphasis on treating diseases or injuries and not patients, an emphasis which flows from focusing on parts of the patient and not seeing him as a whole person. The physician's curing function, so closely related in spirit to the search for knowledge, has too often displaced his caring function, so closely related in spirit to healing. What is needed, in this view, is that an appreciation of the importance of the caring/healing function be fully integrated in medical education and training, so that de-humanizing treatment of patients can be minimized. Teaching, from this perspective, involves not merely the imparting of information and skills, but also of values and attitudes. Physicians thus taught how to heal the patient, instead of his ailment, presumably will be better equipped to influence the patient's behavior in a productive fashion, thereby improving his health.⁷

The familiarity of the complaint that caring/healing may be slighted in favor of curing/search for knowledge does not, of course, trivialize it. And yet the problem may be much easier to state than to solve. For the young physician or medical student must make choices, and the current stress on technical mastery provides a powerful incentive to select the curing/search for knowledge path. That his instructors and

peers may themselves have made a similar choice also may lead to their seeking to influence him to follow their path too. Furthermore, integrating the caring/healing task into the complex and jam-packed education and training program is far from easy. For effectiveness requires that caring/healing not merely be mentioned ritualistically, but be emphasized repeatedly—but not, of course, to the extent that the curing/search for knowledge task seriously suffers.

Some Conclusions

What makes conflicts between healing and the search for knowledge so painful is that each side ordinarily seems entirely laudable. Who but a fool could oppose healing or the search for health knowledge? And so when they conflict, one must choose not a good over an evil, but one good over another. It is a vexing, frustrating business that is impossible to resolve adequately with slogans.

In common speech, we talk of "balancing competing claims" and this provides us with some comfort that we know what we are doing. But, in fact, "balancing" is a treacherously misleading metaphor. It suggests the visual image of a scale, in which the relative weights of two items is clearly determined by the uniform and impersonal force of gravity. Instead, however, in "balancing" claims no force like gravity is available. What happens is that the metaphor is invoked to conceal the inner psychological mechanics of choice, mechanics which are very poorly understood but which almost certainly involve large elements of the irrational and arbitrary. Even numbers, while often helpful, sometimes seem much too incomplete, for the uncertainty of the future and the nature of the possible consequences may prove elusive to the quantifier. While experience provides us with a guide to predict the results of conventional healing practices, for instance, how do we determine the probability or the social results of basic research? Nor can numbers tell us whether we ought to direct our resources toward a healing strategy that offers partial recovery to many people or a search for knowledge strategy that might offer nearly complete recovery to far fewer people.

The illusory nature of the "balancing" metaphor is compounded by the fact that it often forces upon us an unnecessarily limited choice. Balancing a healing strategy against a search for knowledge strategy ignores the competition for resources within each strategy itself, as well as the competition between health interests and other claimants within the society at large. Balancing, in this way, may contribute to blinding the decision maker to problems and opportunities he might otherwise have noticed.

Balancing, in any case, is so subjective an approach

that it supplies little with which a wavering decision-maker can defend himself against aggressive sources of influence. For politicians deciding on health budgets or patients on health treatments, this defect is especially salient. These persons, often very sensitive to their own technical ignorance, face difficult and frequently highly stressful decisions that have to be made. Rigid principles could provide them with something sturdy on which to lean; the gelatinous balancing approach leaves them vulnerable, indeed.

With policy and personal choices to be made, but no generally accepted criteria for choice yet obtaining, disagreements will be unavoidable and controversies intense. It would be naive to hope that answers commanding a consensus will be forthcoming soon. The questions are too new and complex and our society's ethical system much too splintered. Perhaps, in fact, such answers will never be forthcoming. But whether they will or not, choices will continue to be made, and so we owe the problem our attention. Like a persistent winter cold, it will not go away. This forum tonight,

tentative and uncertain as much of our talk has been, may be a part of these first stumbling efforts at coming to grips with these issues. For only by identifying and discussing them today can we hope to deal with them satisfactorily tomorrow.

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Month in Washington

In the name of the "sunshine law," the government released the names of physicians, groups and laboratories that did more than \$100,000 in Medicare business last year. It marked the first breach in the Medicare program's long-standing policy against disclosing such information.

The over-\$100,000 category included 409 physicians, 1,752 medical groups and 58 laboratories. This compared to 2,533 physicians, dentists, and pharmacies listed in the latest Medicaid report of more than \$100,000 intake last November.

The American Medical Association branded the releasing of the names as "only serving to badger a large segment of the profession and to establish guilt by innuendo". AMA Executive Vice President James Sammons, M.D., said "there is a basic dishonesty in the broadcast release of the names of individuals receiving Medicare payments". Dr. Sammons added that if "HEW thinks any physician on this list is guilty of fraud HEW should say so. We will assist in any case where there is good reason to suspect wrongdoing".

Dr. Sammons said the physicians are identified by HEW as individual recipients of Medicare funds, whereas the payments are often for services provided by many others as well. Many of the physicians listed are hospital-based radiologists, pathologists, anesthesiologists. "We would also point out that these services are paid for at a rate set by Medicare and based on prevailing charges two years out of date".

Predictably, press reaction was uneven. Some press took the trouble to check before using the story. Most press did not. All too typical were headlines like this one, from the *Fort Lauderdale Sun-Sentinel*:

"HEW RELEASES NAMES OF DOCTORS ON MEDICARE GRAVY TRAIN."

Few stories bothered to explain that the figures cited are gross, not net; or that HEW's dollar totals included not only payments to the physician but payments made directly to the beneficiary where the beneficiary is responsible for paying the physician's bill.

Having gone through a similar experience in November of 1976 when the Social and Rehabilitation Service made public a list of physicians, dentists, pharmacies, and laboratories that had received \$100,000 or more from Medicaid in 1975; the AMA immediately began checking for accuracy as many as possible of the names and amounts listed as paid to solo practitioners.

By the *Month in Washington* press time, some 166

physicians listed in solo practice were contacted in 30 states and the District of Columbia. Of this group:

- **82 were incorrectly listed as solo practitioners;
- **5 had incorrect amounts attributed paid to them;
- **22 reported both the solo designation and the amount were incorrect.

Some 65.7 percent of the information released on the 409 physicians listed as solo practitioners was therefore incorrect.

Complaints from individual physicians victimized by these inaccuracies poured in to the press. A round-up by the *Associated Press* pointed out some of the injustices done by the HEW release in which two out of three solo practitioners were inaccurately listed.

The *Washington Star* took editorial note of HEW's inaccuracies under the heading: "A SLOPPY PIECE OF WORK."

The physicians contacted by the AMA and state medical societies reported harassment by angry patients, crank telephone calls, children taunted at school as the children of a crook, anonymous threats, attacks by colleagues, and continuing embarrassment within their communities.

A number of Congressmen have inserted remarks into the *Congressional Record* with respect to HEW's disgraceful performance.

HEW Secretary Joseph A. Califano has privately admitted dismay and has publicly stated that a corrected list will be forthcoming shortly.

* * *

The AMA has told the government that fraud and abuse are different problems deserving different treatment.

In a letter to HEW Secretary Califano, the AMA said:

"Frankly, we find it difficult to equate 'abuse' of Medicare and Medicaid programs with some legally definable criminal action. Indeed, it is unfortunate that 'fraud and abuse' have been linked so often in public discussion and departmental releases that the clearly criminal aspects of 'fraud' have migrated to 'abuse' as well."

AMA Executive Vice President James Sammons, M.D., said "fraud" is a reasonably well-defined legal concept—misrepresentation with the intent to obtain money or other goods to which one is not entitled—and has always been clearly subject to legal penalties. Dr. Sammons said examples include billing for services not rendered, etc. "The medical profession has always opposed such practices by its members and urges prosecution of those charged with fraud."



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Month in Washington (Continued)

However, he wrote, abuse is a much more ambiguous term. A "fact sheet" on Medicaid fraud and abuse issued by the Social and Rehabilitation Service states that a provider is "abusing" the program if he files claims and receives payment for services "that are not allowed by federal or state Medicaid laws or regulations." If "abuse" of a program by a provider implies some guilt on his part, this definition is clearly inadequate, since it leaves out any reference to the provider's knowledge of the exclusion, noted Dr. Sammons.

The AMA said the decision as to appropriateness of care "is a professional decision, not a legal one, and we would strongly urge that no attempt be made to bring it within the courtroom, along with prosecution of fraud." Legitimacy and appropriateness of treatment should first be explored by the review committees already established for this purpose at the community level, said Dr. Sammons. "When they agree that the treatment is, indeed, inappropriate and excessive, efforts should be made by his peers to persuade the erring physician to follow a more appropriate course of treatment, but the punitive action should be limited to those already authorized by law—non-reimbursement of excess care and, where the pattern of over-use or over-treatment continues, exclusion of the individual from the program."

He concluded, "We believe that this is both appropriate and sufficient in the way of penalty for actions which the physician himself may consider honest and non-culpable, and we would therefore urge that, while fraud should indeed be prosecuted to the extent of the law, "abuse", in this sense, should be handled within the framework of Peer Review and program administration controls."

* * *

A bill aimed at rooting out fraud and abuse in federal health programs has started down the legislative path in Congress. The AMA applauded the objective, but said the bill is so badly drawn that it allows investigation of "the actions of almost every practicing physician in the United States."

The minority of physicians who abuse Medicare and Medicaid should be brought to justice, the AMA said, but "justice is not served if all practitioners are subjected to harassment and restraint so that a few malefactors may be apprehended."

Edgar T. Beddingfield, M.D., Chairman of the AMA's Council on Legislation, testified before an unusual joint hearing by the health subcommittees of the House Ways and Means and House Commerce Committees. Ways and Means is responsible for Medicare; Commerce, for Medicaid.

To the extent that the legislation was aimed at the "Medicaid mill" it has "far exceeded the mark," said Dr. Beddingfield. "Since this bill has been characterized as the 'Medicaid mill' Fraud and Abuse Bill, practically all group practices could be stigmatized because of the broad application of its provisions."

The broad approach of the bill is "aimed at a large proportion of all practicing physicians, casting its stigma of impropriety upon the tens of thousands of physicians who fall within its purview," the AMA witness said. "Virtually all group practices in the United States would be subjected to the same requirements as the so-called 'Medicaid mill'."

All groups of two or more practitioners would be subject to the extensive disclosure of records provisions, Dr. Beddingfield noted, adding that all practicing physicians who render Medicare and Medicaid services would be subject to review by Professional Standards Review Organizations (PSRO).

Continuing his criticism of the legislation, Dr. Beddingfield said it "endangers the confidentiality of patient records, and certain provisions cannot be justified as needed or even as a wise tool to combat fraud."

To counter charges that his Department has been lax in cracking down on fraud and abuse in health programs, HEW Secretary Califano has called in the FBI.

He said FBI agents will work "full blast" on Medicare and Medicaid misdoings until HEW's own office of investigations is "up to full speed."

Califano made the statements following a report by the Senate Special Committee on Aging contending that illegal kickbacks are "rampant" in the Medicaid program. Summarizing testimony given the Committee last year, the report said nursing homes are the chief offenders, but "increasing evidence points to hospitals, medical practitioners, clinical laboratories and other suppliers."

* * *

The weight of scientific evidence points to a relationship between television violence and increased aggressive behavior in some youthful viewers, the AMA has told Congress.

The AMA called on the TV industry to recognize its social responsibilities, to reduce the amount of violence and to respond with greater sensitivity and diversity in its programming policies. "That television violence represents a serious issue in the mind of the

public is a consideration the broadcasting industry can no longer ignore," declared Robert Stubblefield, M.D., consultant on mental health matters to the AMA.

Testifying before the House Commerce Subcommittee on Communications, Dr. Stubblefield said "television could teach many positive lessons and behavior that would provide alternatives to the violent and anti-social problem-solving so often conveyed in today's programming."

Violence now is a prevalent theme on TV, said the AMA spokesman. He noted earlier testimony of George Gerbner, Ph.D., that there was more violence during the fall season programming than at any other time in the past decade.

Said Dr. Stubblefield: "These results are especially alarming since just three years ago network executives assured another Congressional subcommittee that efforts were well under way to reduce the amount of gratuitous violence."

The AMA believes that the television medium "has not even begun to realize its potential in 'prosocial programming,'" he said.

"In my opinion," Stubblefield added, "the television industry cannot have it both ways—claiming that they merely entertain, facilitate abreaction and ventilation of pent-up emotions, yet denying that they shape and influence behavior. Bluntly stated, shaping and influencing behavior that is stimulating the sale of products is precisely one of the major uses of television."

Thomas D. Morris, a member of the senior staff of the Brookings Institution was named to the newly created post of Inspector General of HEW.

The job was established by Congress last year to oversee a \$25 million program, to find fraud and abuse in various HEW programs, especially Medicaid. Morris will have a staff of 1,000 auditors and 100 investigators.

Morris will focus initially on the broad area of health-care services, including alleged widespread fraud in the Medicare and Medicaid programs, and the student loan programs.

Morris will be responsible both to the HEW Secretary and to Congress. The importance of the post was underlined by having the announcement of Morris' appointment come from the White House rather than the Secretary's office.

The President's Page

As I began to study and evaluate our Society's recent history and its prospective role in our state community, I queried our leadership as to their sense of our goals and roles and our potential for achieving them. Each strongly felt that we should be deeply involved in the process of the delivery of health care and each deplored our failure to become involved. Dr. Spitz even stated in this Journal "if costs are to be contained . . . we must assume the leadership in this endeavor and we must do it now. An answer is needed and if we don't like somebody else's plan, we should be prepared to offer one of our own."

However, all my predecessors failed to receive any support or direction in their efforts. Perhaps the time was not ripe; perhaps we were preoccupied with the naturally pressing demands of malpractice and the F.T.C.

But the issues cry out for some mechanism of action. It is now time to point out the needs and areas of our recognized responsibilities and the vacuums into which we must move. If pointing out the need is not alone sufficient to catalyze the membership to action, it behooves your president to chart the society's options, and to spell out in detail the patterns, the techniques, the format, and the mechanisms that we should employ to achieve these ends.

In this light, I feel that responsibility for spelling out not only the need but the format should be my professed goal. I am totally convinced that we must take a leadership role in the councils concerned with the delivery of health care. It is my deepest conviction that our knowledge in this field and our society's sincerity to render service to the people of the state can contribute greatly to solutions of common problems. Hopefully, our efforts will be met with cooperation so that we in Connecticut can effectively maximize the benefits of the care available while maintaining a reasonableness of cost commensurate with society's capacity to pay.

With this concern paramount, and mindful of the onerous burdens attendant thereon, by the time of this printing I will have proposed to the Council two parallel roads I feel have promise to permit us to work with other providers and planners of the delivery of health care. I shall have suggested that we sponsor seminars to study individual problems of the delivery of care; and that these problems be studied in depth, one by one, so that all understand the problems and thereafter can together attempt to cope with them. Further I am suggesting that our members in their own hospital staffs develop in each hospital a committee to study the cost of the delivery of medical care in their institutions and how to deal with the complex issues involved in delivering care again at a cost commensurate with society's ability to pay without sacrificing quality.

It may be shown that these techniques are not yet acceptable; that they may be too burdensome to a society now in change; that our sincerity may be suspect and our offers rejected out of hand by suspicious, doubting, or critical colleagues. In that case, our society may have to earn credibility by a more constant evidence of our interest and sincerity. In that eventuality, I feel other routes must be followed, other techniques tried. In any case, I feel that leadership must implement, must program, must define and must lead; and I shall endeavor to spend the next year to accomplish these ends.

Isadore H. Friedberg, M.D.

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ISADORE HIRSH FRIEDBERG, M.D.
President

Reflections from the Dean's Office

Robert U. Massey, M.D.

A Royal Commission has been appointed to inquire into Britain's National Health service, and is now hearing evidence. The London *Times* of March 3rd reported testimony from The Hospital Consultants' and Specialists' Association claiming that "the National Health Service should be replaced with a new system based on compulsory health insurance and an independent national health insurance corporation." Further in the article the *Times* states: "The health service has been a great social experiment but now faces a crisis because the premise on which it was founded has proved false, the association says. The universal availability of free health care has not led to a healthier nation and consequently to a reduction in demand for services."

John Lister¹ has reported testimony which the British Medical Association plans to submit, "in which it is argued that the NHS is underfinanced, overorganized, and beset by manpower problems and falling morale." The Royal College of Physicians of London "suggests that the Royal Commission should seek ways of insulating the Service from direct government control, so that recurrent changes of strategy due to changing government policy might be avoided."

Compulsory health insurance is not a new idea. It was proposed to the Reichstag by Bismarck in 1881, and was defeated by the Liberals and Social Democrats. The chancellor twisted arms and succeeded in having his sickness insurance bill passed in 1884, and the German Empire under a conservative government became the first western nation to provide comprehensive health and old age insurance. Compulsory health insurance for workers was introduced in Great Britain in 1911, and was seriously proposed for this country at about the same time. Before the first World War national health insurance was supported by many state legislators and by the American Medical Association. That position changed after the War, but, for the past 30 years, national health insurance has been, in someone's view, just around the corner.

Nevertheless, there is no plan. No one has put together a convincing proposal based upon a vision of how the whole system should work. No one has offered a scheme which can be comprehended in a sitting, or encompassed in a paragraph. The government has supported hospital construction, biomedical research, medical school construction, regional medical pro-

grams, health planning, medicare, manpower development, prepaid medical care, quality control programs, and now proposes to control costs and reduce volume. Each effort has been seen, in its turn, as the major work to be done to improve health and health services, and each has been seen as a necessary step toward a national health policy.

Unfortunately these programs have been undertaken in sequence, each encouraged for a time to great exertions, and then abandoned or at least left, like the National Health Service, "underfinanced, overorganized, and beset by manpower problems and falling morale." In our democracy, this is perhaps inevitable. It is mercifully not possible to hatch great schemes and lay them in the fullness of their maturity upon the entire nation. Only in times of danger can any kind of coherent national policy find general acceptance. And though we have spoken in hyperbole of a crisis in health care, no one believes in it, and few are in any hurry to resolve it.

There is a danger, however. Health manpower legislation was passed last December after almost two years of debate over issues which seemed important, but which had gathered political significance out of proportion to their inherent worth. While the politicians debated, medical schools could not plan, and everyone became irritated with the whole business. As a result, after long delay, the bill was put together quickly and passed, and it was a bad bill.

The same thing could happen with national health insurance. The ninety year experience in Germany may not be helpful. Thirty years of the National Health Service in Britain is instructive, and the testimony before the Royal Commission should be searched for analogues. The experience of the National Institutes of Health, Hill-Burton, Regional Medical Programs, Medicare and Medicaid, Comprehensive Health Planning, Health Manpower legislation, and the National Health Planning Act of 1974 should be examined to see what is working and why there have been failures.

We have before us great social experiments. Before, in our impatience, we encouraged poor legislation, the results of those experiments and the assumptions upon which they were based should be closely examined. Otherwise prejudice, politics, and ignorance will write a bad law.

ROBERT U. MASSEY, M.D., Dean and Professor of Medicine, University of Connecticut School of Medicine, Farmington.

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EDITORIALS

Adjuvant Therapy in Colorectal Cancer

Colorectal cancer is second only to lung cancer as the principal cause of death from malignant disease in American adults. Early diagnosis is essential and screening techniques evaluated by clinical investigators such as Winawer and Sherlock (*Clinics in Gastroenterology* 5:575, 1976) may do much to improve overall treatment results. Recognizing patients at high risk for developing colorectal cancer can result in detection at a stage when lymph nodes are negative, the most significant prognostic factor in this disease.

Adjuvant therapy is most effective in a setting of minimal residual disease. Not only does this imply that all gross tumor has been removed, but also in some animal systems has been defined as a residual tumor burden of less than 1×10^5 cells. Therefore, it would seem imperative that an adequate cancer operation for colorectal tumors is an essential prerequisite to effective adjuvant therapy. Through the years, the debate over the "no-touch" technique of Turnbull versus standard resection has carried a common theme. In either a wide resection of colon and node-bearing mesentery is accomplished and one can expect, in the absence of adjuvant therapy, 5 year survivals in the 50-55% range for Dukes C lesions.

Doctors Nystrom and Viola present a well-designed adjuvant immunotherapy protocol in high risk patients with colorectal cancer. All such protocols have patients adequately staged so that "apples can be compared with apples". In addition, when one looks at non-specific immunopotentiators as an adjuvant arm, it is essential that non-specific as well as tumor-specific immune parameters be evaluated to fully understand the effects of therapy on host immunity. In

colorectal cancer, there is already evidence in the literature of an immune response in lymph nodes draining a primary colon cancer site. Other investigators have shown a host cytotoxic response to tumor cells which can be correlated to stage of disease.

Prospective, randomized controlled studies are the most ideal tools for obtaining solid data to determine the efficacy of adjuvant therapy. Ongoing studies using radiation therapy, chemotherapy and immunotherapy in an adjuvant setting will hopefully point the way to increasing survival in patients with advanced resectable colorectal cancer.

Joel Lundy, M.D.

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Psychiatry and Politics in the USSR

The Council of the Connecticut State Medical Society, at its February meeting, has gone on record as deploring the abuse of psychiatry for political purposes in the Soviet Union. A few comments are in order as to why such a stand was taken, and as to why it was an appropriate stand to take.

The labelling of mentally healthy dissidents as "insane" goes back a long way in Soviet Russia. In Tsarist times, the large network of prison camps and lack of even formal legal redress made such practices largely unnecessary. More recently, however, the existence of certain "freedoms" in the Soviet Constitution and the guarantee of at least perfunctory judicial process have made the psychiatric hospital a more attractive disposition for those the Soviet regime finds intolerable, but not yet formally outside the law.

Soviet abuse of psychiatry first came to the attention of westerners largely as the result of the efforts of a brave man named Vladimir Bukovsky. Bukovsky dared to come to the defense of dissident writers Sin-yavsky and Daniel in the mid-1960s. He was arrested and detained in a mental institution. The "diagnosis" was "sluggish schizophrenia with reformist delusions."¹ While confined, Bukovsky managed to obtain and to smuggle to the West the formal psychiatric "examinations" and other documents concerning several other dissidents then being detained for "insanity." These documents, the authenticity of which is accepted by leading judicial and psychiatric scholars in the West, and which have never been denounced as fraudulent by the Soviet Government, conclusively demonstrate that these individuals suffer from no mental disorder, but rather were incarcerated under false pretenses by the secret police (KGB). These "Bukovsky papers" were translated into English and were published in Volume I of *Abuse of Psychiatry for Political Repression in the Soviet Union—Hearings Before the Committee on the Judiciary, United States Senate, 1972*.² The direct result of Bukovsky's courageous act was a 12-year prison sentence. Bukovsky's term was brought to an unexpected end last year when he was flown to Zurich in exchange for Chilean Communist Party leader Luis Corvalan.

Bukovsky's testimony was followed by that of many others who had themselves been so incarcerated. Famed Soviet gerontologist Zhores Medvedev was imprisoned and labelled insane in 1970. Medvedev's brother Roy was able to quickly mount a worldwide campaign for the release of the beleaguered scientist, and the efforts of these two men were later detailed in the second major sourcebook on this topic—*A Question of Madness*.³

There are now many survivors of Soviet "Special Psychiatric Hospitals" living in the West, and the picture they paint of their experiences in these hell-holes is not a pleasant one.

The pattern seems to be that a given dissident is hounded and harassed for a prolonged period. If he continues to support the cause of civil liberties, or to speak out on behalf of other dissidents, he is arrested and charges are brought under one of the catch-all statutes of 'anti-Soviet activity' or 'hooliganism.' Usually such trumped up charges can be made to stand up under the ambiguous Soviet criminal code. However, in those cases where even a show-trial is thought to be too embarrassing to the regime, the person is referred to the Serbsky Institute of Forensic Psychiatry in Moscow, where he is 'examined' and certified 'mentally incompetent' to stand trial. He is then subject to incarceration in a 'Special Psychiatric Hospital' (SPH) for an indefinite period.⁴

Once in the SPH, the political prisoner is placed on a ward where many of the inmates are in fact criminally insane. He is subject to beating and intimidation by both guards and fellow inmates, whose sadistic inclinations are encouraged by the Hospital authorities. 'Treatment' consists of powerful psychotropic medications, which can profoundly alter the nonpsychotic mind, intramuscular sulfur injections, intended to punish those who disobey, insulin coma therapy, and the notorious 'wrapping' in which the prisoner is wrapped in a wet canvas, which is then allowed to dry and contract, slowly suffocating the victim. All of these facts are substantiated many times over by numerous eyewitnesses from several different institutions.⁵

But why should such things concern western medical and professional societies? Are these not, as Secretary Brezhnev claims, "internal affairs of the Soviet Union," and therefore not subject to scrutiny from outsiders? Our answer has always been and must emphatically be "no." Just as the perverted medical 'experiments' carried out in the Nazi death camps were the legitimate concern of physicians everywhere, so these cruel abuses of psychiatric practice must also be condemned. For the awful truth is that such abuses could not be carried out without some degree of cooperation from the Soviet psychiatric profession.

Sagan and Jonsen, in their recent article on "Medical Ethics and Torture", pointed out that there are a variety of ways in which doctors can knowingly or unknowingly become involved in torture.⁶ They can be used to examine prisoners before, during, and after interrogations in which torture is employed. They can assist in the design of torture devices. They can be involved in the involuntary detention of political dissidents in mental institutions as described above. Sagan and Jonsen provide examples of each type of involvement which are taking place in various parts of the world today. The World Medical Association in 1975 addressed itself to the problem of medical collaboration in torture when it adopted the Declaration of Tokyo. The first point of the Declaration reads as follows:

The Doctor shall not countenance, condone, or participate in the practice of torture or other forms of cruel, inhuman, or degrading practices, whatever the offense of which the victim of such procedures is suspected, accused, or guilty, and whatever the victim's motives or beliefs, and in all situations, including armed conflict and civil strife.⁷

The Soviet practice of psychiatry may be an internal affair. But the involuntary detention of political dissidents in Soviet mental hospitals is an *international* affair. Moreover, it is the duty of western physicians to raise their individual and collective voices

against this practice until it is stopped. The Connecticut State Medical Society, by taking a firm stand on this crucial issue, places itself alongside the medical societies of several other states, the Psychiatric Associations of the United States, Great Britain, and Canada, as well as a number of distinguished publications—the *Medical Journal of Australia*, the *Lancet*, the *British Medical Journal* and others. The next major confrontation in this struggle will take place this coming August in Hawaii, at the meeting of the World Psychiatric Association. At the WPS's last meeting in 1971, objections from the Soviet delegation managed to quash discussion of the issue of psychiatric abuses. Only strong voices from western delegations will succeed this year. We urge our psychiatric colleagues to write to their representatives on the state and national level in support of a resolution on psychiatric abuses at the WPA convention. And we urge all of our members to continue to speak out against such unjust and immoral practices, for only in this way can we at last pronounce an end to the abuse of psychiatry for political purposes. Those desiring further information, as well as suggestions for action, are urged to contact either the Fairfield County Physicians for Soviet Jewry, Eric Garver, M.D., Chairman, 4200 Park Avenue, Bridgeport, CT 06604, or the New Haven Medical Mobilization for Soviet Jewry, Carl I. Schoenberger, M.D., Chairman, 1184 Chapel St., New Haven, CT 06510.

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Risks of Estrogens in Obstetrics

Hardly a day passes without a dire warning of cancer risks to a group of people who have been exposed, knowingly or not, to a recognized or alleged environmental carcinogen. Those who sound the alarm seldom give much information about the real size of the risk. Practicing physicians must deal with the anxieties created in their patients by these fear-producing allegations.

In recent years, leaders among medical specialists have taken the initiative in planning and participating in clinical studies that can help answer their own and their patients' questions about cancer risks. A notable example is the action taken by the Connecticut Section of the American College of Obstetrics and Gynecology (ACOG) two years ago to initiate a clinical research study of the effects on children of exposures in-utero to exogenous estrogens. This medication had been recommended in the 1940's to reduce risks of abortion (Smith, 1948), and was given quite widely during pregnancy until the 1960's when the first cases of adenocarcinoma of the vagina in young women were identified and it became clear that in-utero exposure to diethylstilbestrol had sometimes caused serious or fatal cancers. (Herbst and Scully, 1970).

Because the nature and size of the risks are still poorly defined, Connecticut members of ACOG went to the research community in 1975 to suggest a partnership operation in clinical epidemiological research on these critical questions. State resources included: the Connecticut Tumor Registry (CTR) with 40 years of case records assembled with cooperation of physicians throughout the state; the Connecticut Cancer Epidemiology Unit (CCEU), the research arm of CTR activated in 1974 and attached administratively to Yale's Department of Epidemiology and Public Health; and the Yale Comprehensive Cancer Center. Ideas become reality through people. In this case, ACOG's Stephen Katz went to Yale's John Morris, who came to CCEU's Wister Meigs who went in turn to CTR's John Flannery and to the late Deputy Health Commissioner Harold Barrett. The partnership was open for business and the federal research establishment has responded with funds for Meigs and Watman to conduct a study of cohorts determined by record searches. This will compare the experiences of women and offspring exposed to exogenous estrogens during the mothers' pregnancies with those not exposed. These cohort lists will be determined through the cooperation of physicians practicing in this State.

The investigators have begun to collect data from records of physicians who have agreed to take part. We welcome the invitation of the Editor to bring the study to the attention of readers of *Connecticut Medicine* and to mention what we see as its strong and weak

points. Strengths include its origin, namely concerned practicing physicians, and the unique clinical epidemiological research resources of this State. The need for active, continuing support from practicing physicians could be a weakness if any of the partners allow other, newer concerns to crowd this one out of the way.

The initial scientific focus of the study will be on cancer. Have mothers who received estrogens in large doses during pregnancy, or their children, male or female, exposed in-utero, shown greater (or less) or different patterns of cancer experience in the ensuing 10 to 25 years than those not similarly exposed? Recent preliminary review of CTR cases showed only one definite case of adenocarcinoma of the vagina attributable to in-utero estrogen exposure. If the excess cancer risk from estrogen use during pregnancy is as small as this might suggest, it is vital information for practicing physicians. But no one has had the opportunity previously to quantify the overall cancer experience of groups of exposed persons through use of a population based cancer registry of the quality of CTR. Until this study is finished, we cannot give physicians the necessary scientific facts to use in advising their patients.

A related focus will be on a vaginal adenosis. This condition is alleged to have been induced in women with a history of in-utero estrogen exposure, at rates reported variously as a few to almost 100% of exposed women. Practicing gynecologists who take part in this study will be helping to define vaginal adenosis and to establish design criteria for an extension of this work to explore both the quantitative relationship of vaginal adenosis to in-utero estrogen exposure, and, prospectively, the questions whether or to what extent vaginal adenosis is pre-cancerous.

At this time, the project needs cooperative involvement of any physician in Connecticut who has records of patients who received estrogens during pregnancies that occurred between 1947 and 1969. Project staff are providing whatever help the practicing physicians require to extract data from records of both patients and suitably selected controls. Control cases are essential for scientific validity. No patients will be contacted by project staff unless the treating physician recommends it for his/her own follow-up purposes. Any such contact will conform with established CTR fellow-up practices. No names or personal identifying information will be used or disclosed except as authorized by cooperating physicians and within the confidentiality regulations of the State Department of Health.

The investigators will welcome questions, comments, criticisms and participation! The work was

initiated by practicing physicians and it will succeed to the extent that physicians take part.

J. Wister Meigs, M.D.

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Francine Watman, M.A.

Research Staff Scientist, Field Studies Director, Connecticut Cancer Epidemiology Unit

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Medicredit—1977

The American Medical Association will support a comprehensive national health insurance bill in the new Congress, just as it has in past congresses. . . . AMA delegates approved the reintroduction of such a bill, based on the Association's 15 guidelines for national health insurance.

Those 15 points are: (1) Minimum federal involvement in administration of NHI. (2) State jurisdiction with respect to licensure and certification of professional health personnel and regulation of insurance. (3) Minimum federal dollars in financing of comprehensive coverage at least possible cost. (4) Funding through federal, state, and private funds including (a) employer-employee contributions for private health insurance, and (b) an individual tax credit as applied for full health care protection. (5) No added Social Security tax for financing. (6) No administration by Social Security (7) Cost sharing by participating individuals and families, and a subsidy for the indigent, scaled according to income. (8) Use of private insurance on risk and underwriting basis. (9) Comprehensive coverage, basic and catastrophic, for the entire population. (10) Pluralism in methods of health care delivery. (11) Cost controls as appropriate. (12) Quality control as appropriate. (13) Continuity of benefits. (14) Coordination of benefits. (15) A separation of medical and institutional components of financing, so that the separate costs are ascertainable.

Letters To The Editor

Letters to the Editor are welcomed and will be published, if found suitable, as space permits. Like other material submitted for publication, they must be typewritten *double spaced* (including references), must not exceed 1½ pages in length and will be subject to editing and possible abridgment.

SMOKING AND NON-SMOKERS

To the Editor: Congratulations on a clear, concise editorial on smoking and the non-smoker. It has been a long uphill fight for the non-smoker to get the point across that he also has some rights. Because of the recognized relationship of smoking to throat and lung cancer, we physicians should be the leaders in a campaign to educate the smokers of the inherent danger. It is especially difficult in convincing the female of the species and this might be attributable to women's lib. However, I feel that by proper example we can encourage all groups, public and private, that a smokeless environment is a healthier and happier one. It would be helpful if widespread publicity was given to the efforts of physicians to control smoking in their own assemblies.

Timothy L. Curran, M.D.

Hartford, CT

OBFUSCATION

To the Editor: Dr. Blackburn's article, *Concepts and Controversies* about the Prevention of Coronary Heart Disease (*Conn. Med.* 41:7, 1977), is a masterpiece. A masterpiece of medical obfuscation; a magnificent example of what Dr. Michael Crichton bemoans. I am sending him a copy because I want him to have the fun of reading a medical piece which is so gloriously assinine [*sic*].

Because no editor could possibly have allowed Dr. Blackburn's paper to mature into galleyproofs—much less be printed in its present form—I must conclude that the article is meant to be funny. Therefore, I congratulate the editors of *Connecticut Medicine* for having wisely included satire as a regular feature. There is far too little humor in medical journals today, and I am delighted to see *Connecticut Medicine* take the initiative in providing amusement for its readers. Keep up the good work!

Peter H. Gott, M.D.

Lakeville, CT

CORONARY HEART DISEASE

To the Editor: Dr. Blackburn's recent article, *Concepts and Controversies* about the Prevention of Coronary Heart Disease, was both thought provoking and informative. The author succeeds in pointing out the difficulties in interpreting epidemiologic relationships between coronary heart disease and the plethora of risk factors associated with it. His assessment of the problems inherent in demonstrating the efficacy of applying these associations in the primary prevention of this disease are presented well. It is distressing to conclude from the article that it will be a long time before public health efforts can be applied to prevent coronary heart disease on a truly rational basis.

I commend your efforts in securing this noted cardiologist-epidemiologist to present his thoughts on this difficult subject.

Edward J. Bernacki, M.D.

Torrington, CT

CONNECTICUT MEDICINE

To the Editor: I want to tell you how much I recognize and appreciate your efforts to make *Connecticut Medicine* a respected journal which is filling an important place in our professional family. I have heard many favorable comments from professional colleagues and faculty—and even from laymen who have medical interests.

Robert U. Massey, M.D.

Dean and Professor of Medicine

University of Connecticut School of Medicine
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THE PHYSICIAN AND HOSPITAL COSTS

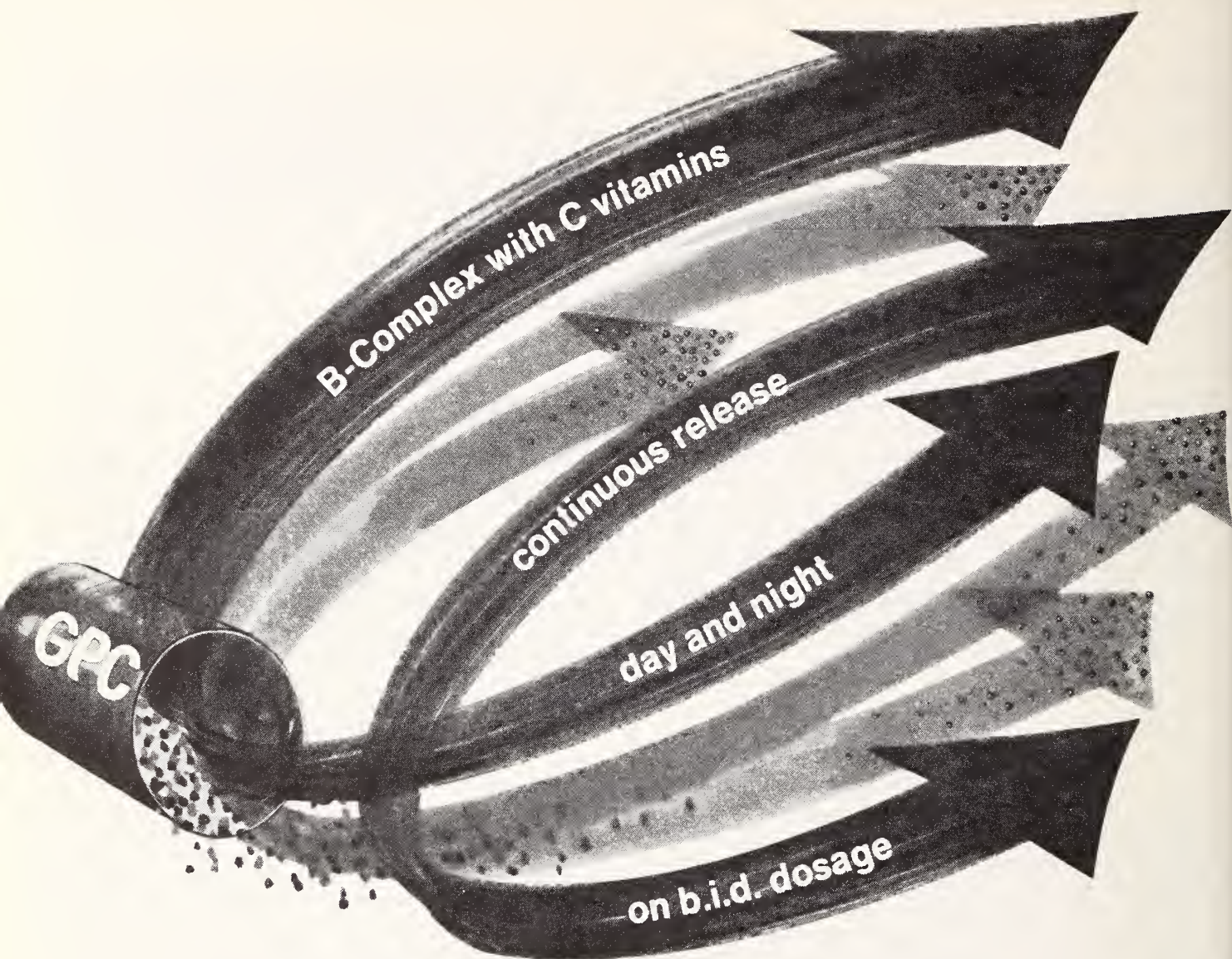
To the Editor: In the report of the President to the House of Delegates¹ Dr. Hilliard Spitz addresses some of his comments to hospital costs. He deplores the rising costs of medical care, particularly in hospitals and raises a few questions, namely the costs of emergency room care versus that in private physicians offices, the costs of full time hospital specialists, and regionalization of services. All of these are sound questions but they all have basically the same answer; and this seems to me has been largely avoided by Dr. Spitz. The same vital point is avoided both by the Council of the Connecticut State Medical Society² and the proponents of the Commission on Hospitals and Health Care.³

The problem I am addressing is the paramount role of the physician in promulgating the demands for medical and hospital services, and his apparent unwillingness to accept this as a major cause of the rise in hospital costs. Is it the Hospital Administrator or the Board of Trustees who order great masses of frequently repeated laboratory isotope imaging or radiologic examinations? Is it only the in-hospital specialists who demand sophisticated inhalation therapy and related diagnostic procedures? Did the hospital personnel invent the costly and toxic chemotherapy for cancer?

What society is trying to do is to limit the costs of medical care without anyone making responsible decisions as to which costs are to be cut and which procedures eliminated. The practitioners, if the Council discussion³ is correctly presented, take a detached view as if they had no responsibility for the increasing costs, and even more surprisingly as if they were not to be involved by the cost-containing decisions. Assume, for example, that the Cost Commission sets a ceiling of 9% increase annually on hospitals, and that this is distributed equably through all hospital departments. At present hospital clinical and radiological departments are increasing their volume at over 10% a year. Even with maximum increases in automation and efficiency there will come a limit at which these diagnostic departments will need to ration tests—and this will be the signal for a sudden awareness by the clinical departments of the consequences of their earlier disinterest! Will the hematologists cut down on marrow aspirations, the surgeons on biopsies and the internists on blood cultures? Who will be first?

As far as I am aware the major thrusts of Audit Committees, Review Committees, and the wide variety of private and governmental agencies who appear weekly to check up on everything is to assess quality of care, to recommend more procedures, more controls, more services; and somehow these always cost something. How many audit or utilization committees have ever studied the cost—benefit ratio of even a single procedure; or suggested that tests or treatments could have been fewer rather than more?

This is not calculated to be a popular view-point; physicians generally have been taught to go all-out to try every test, to give every treatment. Until, as a profession, we undertake some practical studies and solutions which will enable us to pick areas for economies, we are inviting the type of "ceiling" controls I described



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above; these will be inexpert and probably often inappropriate—but, we will have brought it on ourselves. Finally, when hospital costs have been “controlled”, how long before individual and group practices will also be in the same position?

Chief of Pathology,
Norwalk Hospital,
Norwalk, CT

Roy N. Barnett, M.D.

REFERENCES

1. Spitz H: Report of the President to the House of Delegates at its Semi-Annual Meeting, November 17, 1976; *Conn. Med.* 41, 50-52, 1977
2. Summary of Actions; Council Meeting Wed Dec 15, 1976; *Conn Med* 41, 124, 1977
3. Howard D and Jarrett JE: The Connecticut Commission on Hospitals and Health Care; *Conn Med* 41, 105-112, 1977

RESEARCH INVOLVING PRISONERS

Health, Education, and Welfare Secretary David Mathews has released the Report and Recommendations on Research Involving Prisoners compiled by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

The Commission was established in late 1974 under the National Research Act, Public Law 93-348, and was required to make recommendations with regard to research on human subjects generally, and on prisoners, the mentally infirm, psychosurgery, and the fetus. Recommendations on fetal research appeared in August 1975 and were promptly implemented by DHEW.

The Commission has carried out an extensive study of the nature of research on prisoners conducted in the United States. In addition, Commission members made visits to four prisons, including interviews with inmates who had been research subjects. Consultants to the Commission conducted similar studies at five additional prisons. Public hearings were held to hear testimony from prisoner advocates, prisoner legal services, research scientists, and members of the general public.

The Commission also sponsored a National Minority Conference on Human Experimentation to insure that the voices of the various minority groups would be heard. Finally, in a series of deliberative meetings open to both press and public, the Commission considered its own observations and those of experts who studied foreign methods of non-prison drug testing, alternatives to the use of prisoners, and sociological perspectives in the use of prisoners.

In summary, the Commission's five recommendations are:

Studies of the causes and effects of imprisonment and of prison life may be conducted pro-

vided that the risks are minimal and do not seriously inconvenience the subject.

Research may be conducted on new or accepted methods of diagnosis or treatment which are intended to improve the health or well-being of the individual prisoners and have a reasonable chance of success.

Other types of research may not be conducted unless the research is found by the head of a responsible Federal department, in consultation with a national ethical review body, to fulfill an important social and scientific need. The reasons for involving prisoners must be compelling, and the conditions of imprisonment such as to insure a high degree of voluntariness on the part of the subject and openness on the part of the correctional institution.

The investigators must in all instances be competent, the research facilities adequate, and the research subject to review by an institutional review board including among its members prisoners or prisoner advocates as well as meeting all other requirements for institutional review boards.

Current research projects, subject to regulation by the Secretary of HEW, that cannot meet these requirements should be permitted to continue not longer than one year from the date of publication of the recommendations, or until completed, whichever is earlier.

Under the terms of the National Research Act, the Secretary must seek public comment on these regulations before either rejecting or implementing them. Either action must be completed within a period of 180 days.

This study was supported by NIH's Division of Research Resources H.E.W., Public Health Service, Bethesda, MD., January 1977.

NOTICE TO CONTRIBUTORS

Members of The Connecticut State Medical Society reading papers before other organizations are requested to submit their papers to the JOURNAL for consideration by the Board of Editors for publication. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult **INFORMATION FOR AUTHORS**. This material may be obtained from the *Journal* office. Adherence to the instructions will prevent delays both in acceptance and in publication.

Please send them to:

J. Alfred Fabro, M.D., Editor
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Summary of Actions

Council Meeting

Wednesday, April 6, 1977

I. Attendance

Present in addition to the Chairman, Dr. D.A. Grendon, and the Vice Chairman, Guy W. Van Syckle, were: Drs. Spitz, Friedberg, Freedman, Backhus, Nolan, Canzonetti, Cramer, Fabro, Kamens, Harkins, James, Mendillo, Krinsky, Sonnen, Whalen, McGarry, Ahrens, Sadowski, Magram, Eslami, Parrella, Zlotsky and Middleton.

Also present were: Mrs. Lindquist, Mrs. Arafeh (CSMS Auxiliary), Dean Massey (UConn Medical School), Mr. Tomat (FCMA), Mr. Sweeney, Mr. Brunell and Dr. Richards.

Absent were: Drs. Johnson, Hess, Bradley, Beck, Vidone and Barrett.

II. Routine Business

Approval of Minutes

As published and distributed, it was VOTED to approve the minutes of the meeting of March 10, 1977, with the following amendment: Under "Reports of HSA Activities" on Page I, it is to be recorded that Isadore H. Friedberg, Newington, is chairman of the Statewide Professional Standards Review Council; *not* of the Statewide Health Coordinating Council (as published).

Life Memberships

It was VOTED to approve applications for Life Membership received from the following eligible Active Members:

William Grillo, 393 Prospect Street, Willimantic
Abraham I. Levine, 26 Wilson Avenue, Rowayton
Samuel R. Millen, 545 Dixwell Avenue, New Haven
Samuel Turetsky, 2357 Fairfield Avenue, Bridgeport
R. Edward Vioni, 3450 Main Street, Bridgeport
Sylvia Weiner, 99 Pratt Street, Hartford

Date of Next Meeting

The incoming President, Dr. Friedberg, set the date for the next (organizational) meeting of the Council for Thursday, May 12, 1977.

Report of Connecticut AMA Delegation re Promotion of AMA Membership

It was VOTED to approve a subject report submitted by the Connecticut AMA Delegation, which outlined a number of ongoing and projected activities designed "to make the medical profession in Connecticut aware of the reason for, and advantages of, joining the American Medical Association". In summary, the report made reference to promotional activities being carried on by AMA Delegates, Alternate Delegates and CSMS Officers using a "speakers' bureau" format; the efforts of the Society's Committee on Cooperation with the Medical Schools of Connecticut to interest medical students in participating in activities of the Society and the AMA; the extensive space in the Journal which is being devoted to information about the AMA and about its activities taken on behalf of *all* physicians, whether AMA members or not; the continuing effort being made by the Connecticut Delegation to have AMA mail the issues of *AMNews* that precede and follow meetings of the AMA House of Delegates so that *all* physicians may be made aware of items on the agenda and the actions taken thereon (this mailing was done experimentally before and after the December, 1976 meeting in Philadelphia at a cost to AMA of \$25,000); publication of the "Report of the AMA Delegates" in the Journal; etc. It was further VOTED to bring the foregoing summary to the attention of the CSMS House of Delegates on April 27 as the subject report of the Council (Old Business) as directed by the House at its semi-annual meeting last November.

In a related action, it was VOTED to obtain and distribute to members of the Council copies of the "AMA Newsletter", a weekly report from the Executive Vice President's Office, for a trial period of four months. The program will be assessed for continuance at the end of the trial period.

Policy re Publication of Obituaries in the Journal

The Council VOTED to accede to the request of the NHCMA Board of Governors (a similar request was received subsequently from the NLCMA 1977 annual membership meeting) that the former Journal policy

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re publication of obituaries be resumed; i.e., that if written and submitted by colleagues, obituaries for deceased members will be published. During the past year, obituaries have been limited to officers of CSMS and to presidents of the component County Medical Associations.

Report on “Countersuits” – Committee on Professional Liability

It was VOTED to receive and approve a subject report submitted by the Committee, and transmit the report to the House of Delegates with the Council’s recommendation that the House approve the report and authorize its implementation as a function of the Committee on Professional Liability.

HCMA Communication re “Pronouncement of Death” Problems

It was VOTED to receive a communication from the Hartford Association’s Committee on Community Health which brought to the Council’s attention certain problems that have come to HCMA’s notice concerning pronouncement of death and the signing of death certificates by a physician other than the patient’s own attending physician, and requested that the Society join with HCMA representatives in attempting to resolve the problems in consultation with the State Chief Medical Examiner, Dr. Elliot Gross. It was further VOTED to communicate to Dr. Gross that the Society, if desired, will sponsor and arrange a meeting at which he and CSMS and County Association (8) representatives can discuss the entire matter and seek appropriate remedies.

CSMS Policy re Professional Liability of Referring Physicians

The Council was apprised of an actual instance in which a physician who had advocated treatment of a patient by a dental surgeon of the family’s choice was named as a co-defendant in a malpractice action brought against the surgeon and other parties to the operation. As a consequence of his referral, a portion of the settlement was charged to him. Following a considerable period of discussion, it was VOTED to adopt a motion as follows: “That the Council of the Connecticut State Medical Society express the opinion that referrals made in good faith by a physician should not reflect on the liability exposure of the referring physician; that the Council request the Committee on Professional Liability to research at once, in consultation with its legal counsel, the methods by which the Council’s subject opinion can be implemented; and that the Committee report to the Council within 60 days (30 days if possible) a complete plan

for implementing the subject opinion or a detailed explanation as to why such a plan is not feasible.

CSMS Nominations for Gubernatorial Appointments

Hilliard Spitz, the President, presented a summary subject report which indicated that, in the past year or two, almost none of the physicians nominated by the Society for various state agency posts had been appointed to those posts by Governor Grasso. Expressing concern about this development, the Council VOTED to communicate to the Governor its disappointment that so few of the Society’s nominees have been given appointments during the past year or so and to request an audience with her at which the President, the President-Elect and the Vice President would have opportunity to discuss this matter.

Raised Committee Bill No. 1651 – An Act Concerning the Commission on Hospitals and Health Care

The Council was informed that the Assembly’s Committee on Public Health and Safety had given a joint favorable report to the subject bill, and that it would probably be voted on by the Senate and House within a week or ten days. The Council found highly objectionable three provisions of the bill as follows: (1) The qualifications of a physician Commissioner were changed from “a practicing licensed physician” to “A LICENSED PHYSICIAN CURRENTLY ENGAGED IN A NON-HOSPITAL BASED PRIMARY CARE PRACTICE”; (2) The Society was eliminated as a source of nominees for physician membership on the Commission; and (3) The incumbent Commissioner nominated by the Society, appointed by the Governor to a five year term on 7/1/77, would be ousted and replaced by a newly appointed (7/1/77) physician engaged in a primary care practice.

Following lengthy discussion, the Council VOTED to communicate in writing to the Governor and all members of the General Assembly the Society’s strong protest and objection regarding the subject provisions of Raised Committee Bill No. 1651 and urge them to take appropriate action to delete the provisions from the measure; i.e., to return the Society’s privilege of nominating physicians for appointment to Commission membership.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on April 6, 1977. Detailed minutes of the meeting are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

BOOK REVIEWS

Bereavement: Studies of Grief in Adult Life. by Colin Murray Parkes, International Universities Press, Inc., 1972. 233 pages. \$10.00.

Based on the author's research studies, this book is remarkable in two ways. First it illustrates the value of relatively simple observations continued over a number of years in elucidating the natural history of a little recognized major hazard to mental health. Second, it shows how an understanding of the grief process can be of immense value to all whose work brings them into contact with the bereaved. Dr. Parkes has made a cogent case for a drastic reappraisal of our societies' attitudes towards the bereaved and gives us guidelines on how to improve our care.

Written with a minimum of jargon, he introduces us to the clearly explained general concept that grief has a natural history. Dr. Parkes describes the typical manifestations of normal grief, with case histories to illustrate and explain the phenomena experienced by the bereaved. Parkes describes phases of shock and numbness; anger and guilt; yearning and protest, depression and submission; and finally acceptance and the formation of a new identity. Many readers will recognize patterns of reaction and behavior which they themselves have experienced in their own episodes of grieving. Particularly important for physicians to understand is the anger directed toward anyone involved in the loss. God and the doctors come in for a lot of angry criticism since both are seen as having power over life and death. "I still go over in my mind the way those doctors behaved," said one widow who accused them of ignoring significant symptoms. Doctors need to realize that much of this emotion is displaced onto them as easily available targets.

It is important for those who attempt to help the bereaved to know what is normal. Bereaved people are so surprised by the unaccustomed feelings of grief that they often ask, "Am I going mad?" or "Is it normal to be like this?" Fortunately this book helps us reassure people of their normality.

Against carefully thought out background of normal grief, the reader is then helped to identify the hallmarks of abnormal grief. It is clear that such recognition is an essential first step to the prevention of long range morbidity. Dr. Parkes helps us to identify those who are at 'high risk' in terms of getting into difficulties. Absence of grief in a situation in which it would have been expected, episodes of panic, lasting physical symptoms, excessive guilt or excessive anger or the persistence of intense grief beyond the expected period—these should be taken as signs that all is not going as it should and maybe the signal to get additional help.

If bereavement can have detrimental effects upon physical and mental health, what can be done to prevent these effects from occurring? Most doctors would regard it as one of their roles to give help and advice to the bereaved, but they have received little formal training in this area of service. A chapter is directed to helping the bereaved, describing how volunteer self-help groups and professional skills can blend together in a preventative outreach.

Dr. Parkes' studies reveal a common theme in the human beings' behavior following the loss of a loved one and he describes behavioral phases in a lucid fashion. If we as physicians are to understand and support our patients as they suffer with their reactions to a loss, we need to be able to recognize normal grieving processes and distinguish them from the potentially dangerous.

Sylvia A. Lack, M.B., B.S.

Medical Director of Hospice

In Memoriam

Farmer, Douglas A., Harvard Medical School, 1942. Dr. Farmer was a surgeon in the New Haven area since 1967. He was chief of surgery at St. Raphael's Hospital since joining the hospital in 1967, and helped plan a major portion of the hospital's new Verdi Memorial Building. At the time of his death, Dr. Farmer was president of the New Haven Chapter of the American Cancer Society, president-elect of the Connecticut Chapter of the American College of Surgeons and treasurer of the New England Surgical Society. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Farmer died March 29, 1977, at the age of 60.

Harshbarger, Isaac L., University of Virginia, 1922. Dr. Harshbarger was a retired surgeon who practiced in Bridgeport for more than 30 years. He served as president of the Bridgeport Hospital staff and as chief of surgery, and also served as president of the Fairfield County Medical Association. Dr. Harshbarger was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. He died March 14, 1977, at the age of 79.

Oesau, Harold T., Sr., Jefferson Medical School, 1926. Dr. Oesau was a family practitioner in the Fairfield area since 1928. He served as a private in World War I. He was a member of the Fairfield County Medical Association and the New Haven County Medical Association. Dr. Oesau died February 20, 1977, at the age of 76.

Walker, W. Bradford, Yale Medical School, 1920. Dr. Walker was a well-known physician in general practice in Litchfield County for over 50 years and a leader in state and community health services. He was president of the Litchfield County Medical Society in 1946-47 and was secretary from 1933 to 1945. He was also president of the Connecticut State Medical Society in 1948 and secretary from 1949 to 1955. He was a member of the Litchfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Walker died March 18, 1977, at the age of 81.

Woodford, Francis B., Yale Medical School, 1924. Dr. Woodford was a general practitioner in the Fairfield area since 1926 and served in both World War I and World War II. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Woodford died March 20, 1977, at the age of 73.

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiry of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511, (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine*.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

Dermatology: Two fully-equipped offices available, one in New Britain and one in Bloomfield. Contact 677-7612 or 225-6464.

Emergency Medicine: Contact Melvin D. Orlins, M.D., Norwalk Hospital, Norwalk, CT 06856. 203-838-3611, Ext. 596.

Family Practice: Long established practice of solo physician about to retire, available in New Haven, Contact CSMS.

Family Practice or Internal Medicine: So. Central Connecticut opportunity for physician to start practice in an ideal community with demonstrated need. Office space available, with equipment, for two physicians. Favorable lease arrangement. Affiliation with community hospital-medical school. Attractive residential area, excellent educational, cultural and recreational opportunities. Available July 1977. Send C.V. to CSMS-FP-IM.

Internal Medicine: Third Internist desired for active two man practice in S.E. Ct. shoreline town. Prefer general internist interested in patient care. Early availability preferred. Write CSMS-IM.

Internal Medicine (Cardiology): Wanted for private practice. Non-invasive technique and organizing a cardiac lab for stress testing. Complete curriculum vitae. Reply P.O. Box 656, Middletown, CT 06457.

Internal Medicine (Geriatrics): Part time. Capable and interested in supervision and teaching of house staff and medical students in a multi-disciplinary setting. 20 hours per week. Write CSMS-I.M.-Geriatrics.

Internists, Family Practitioners and Pediatricians: To attract physicians to practice in areas of need. John E. Donnelly, M.D., The University of Connecticut Health Center, Farmington, CT 06032.

Internal Medicine (Primary Care): Needed at Park City Hospital, Bridgeport. Private practice with contractual arrangements for first year income. Contact Mr. John Jacobs, Director of Personnel, 203-368-0201.

OB/GYN: Contact Mr. H.L. Green at Winsted Memorial Hospital, Winsted, CT 06098. 379-3351 ext. 270 for details.

Pediatrics: Excellent partnership opportunity in attractive mid-Connecticut community. Contact CSMS.

Primary Care Physician: Board Eligible or Certified in Internal Medicine, experience in Ambulatory Care. For 900+ bed hospital in Central Ct. Responsibilities primarily supervisory and teaching in Primary Care Unit, Medical Clinic and Medical Section of Emergency Department. Work in Team of Physician, Nurse Practitioner and House Staff. Send CV and salary requirements to Dr. Kenneth Godlash, Director Medical Ambulatory Services, Hartford Hospital, 80 Seymour Street, Hartford, CT 06115.

Pediatrician: Needed to help general internist take over for general practitioner in fast growing Danbury area. Office 10 minutes from the hospital. Call 203-746-3300.

Psychiatry (Staff, Child and Senior): 80 bed Psychiatric Hospital, serving general psychiatric patients, alcohol and drug dependent persons and adolescents. Requires full time physicians to work with interdisciplinary team. Interest in psychoanalytically oriented psychotherapy desired. Opportunity to participate in ongoing Neurochemical Research and to pursue own research. Time provided for Faculty Appointment at University Send C.V. to Robert E. Becker, M.D., Medical Director, Hall-Brooke Hospital, Westport, CT 06880.

PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

INTERNAL MEDICINE

July 1977. Age 29. Bd. cert. Group or associate practice within 45 minutes of NYC. Int. and Res. N.Y. Med. College-Metropolitan Hosp. Steven R. Koval, M.D., 3221 Oxford Ave., Bronx, NY 10463.

July 1977. Age 35. Conn. License pending. Interested in ER and/or primary care. Int. and res. at St. Raphael's. Contact CSMS-IM-JRZ.

Cardiology: July 1977. Age 31. Bd. elig. Solo, group, associate or institutional practice in medium or small community. Bhola N. Banik, M.D., Fairhaven Dr., W., Apt. G-2, Nesconset, NY 11767.

Cardiology: July 1977. Age 32. Bd. cert. Hospital-based solo practice in large or medium community. Fellowship at Kingsbrook Jewish Med. Ctr. Harrison Y.N. Yang, M.D., 1901 Dorchester Rd., #5B, Brooklyn, NY 11226.

Gastroenterology: July 1977. Age 31. Bd. cert. Wishes to do at least 50% gastroenterology. Conn. license. Bernard M. Aaron, M.D., 44 Gristmill Road, Kings Park, NY.

Hematology-Oncology: July 1977. Age 32. Bd. cert-IM-Hematology, elig-Oncology. Group or associate practice. Barry C. Freeman, M.D., 33 E. 75th St., New York, NY 10021.

OPHTHALMOLOGY

July 1977. Age 32. Bd. elig. Solo, group or associate practice. Also interested in purchasing a practice. M.D. from Albert Einstein. Howard Z. Marton, M.D., 1010 Old Towne Dr., St. Louis, MO 63132.

May 1977. Age 30. Bd. cert. Group or associate practice in medium sized community. M.D. from McGill. Robert Wener, M.D., 142 Aldred Place, Hampstead, Quebec H3X 3J3.

ORTHOPEDIC SURGERY

July 1977. Age 29. Bd. elig. Solo or associate practice in medium or small community. M.D. from NY Med. College. Int. and res. at Montefiore Hosp., Bronx. Roy B. Friedenthal, M.D., 6049 Huxley Avenue, Bronx, NY 10471.

OTOLARYNGOLOGY

July 1977. Age 34. FLEX. Solo, group or associate practice in medium community. Fellow at Lenox Hill Hosp., NY. Jagadish D. Navare, M.D., 3409 150th St., Flushing, NY 11354.

PATHOLOGY

Three months notice. Age 36. Nat'l Bds. FLEX. Int. Manchester Memorial Hosp., Conn. Res. Baptist Hosp., Winston-Salem, NC. Group, associate or institutional practice in medium community. Ramesh P. Dave., M.D., 18 Terry Dr., Jacksonville, IL 62650.

Available now. Age 32. Bd. elig. Res. Norwalk Hospital, Conn. Licensed in Conn. Full-time position in a group or associate practice, but willing to work part-time or cover weekends provided the place is a commutable distance from Rockville, Conn. Contact-CSMS-Path.-SMD.

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July 1977. Age 27. Bd. elig. M.D. from Yale. Int. from Univ of Rochester. Res. at Strong Memorial Hosp., NY. Group or institutional practice. Leonard Banco, M.D. 104 Community Manor Dr., Rochester, NY 14623.

July 1977. Age 27. Nat'l Brds. Int. and res. at Cincinnati Children's Hosp. Solo, group or associate practice in large or medium community. Julius Edlavitch, M.D., 3209 York Lane, Cincinnati, O 45215.

August 1977. Age 31. Bd. elig. Int. and res. Rhode Island Hospital. Fellowship Sacramento Med. Ctr. Desires either general pediatrics or hematology-oncology in group, associate or institutional practice in large or medium community. John Ertl, M.D., 4827J Parkway, Sacramento, CA 95823.

July 1977. Age 30. FLEX. Bd. elig. Int. and res. St. Joseph's Hosp., Illinois. Prefers community near UConn. Solo, group or associate practice. Contact CSMS-Ped.-R.B.G.

July 1977. Age 28. Bd. elig. Int. Mt. Sinai, Florida. Res. Brookdale Hospital, NY. Fellowship Univ. of Tennessee. Group or associate practice in large or medium community. Oravan Pathomvanich, M.D., 3186 Steele St., #6, Memphis, TN 38127.

Available now. Age 28. Bd. cert. Full or part time in general pediatrics. Associate or institutional practice. Contact CSMS Ped.-AS.

July 1977. Age 29. Bd. elig. Int. and res. Lincoln Hosp., Bronx. Res. at Bridgeport Hosp. Group, associate or institutional practice in large or medium community. Telephone Bridgeport 1-576-8731.

Diagnostic: July 1977. Age 40. Bd. cert. M.D. from Tufts. Int. Boston City Hosp., Res. Letterman Army Med. Ctr. Presently in active duty. Richard B. Circeo, M.D., 369 Coral Sea Circle, Ft. Lee, VA 23801.

Available anytime. Age 52. Bd. elig. Res. Franklin Hosp., Pa.
Associate or institutional practice. Luis A. Barranco, M.D.,
Throckmorton Clinic, Box 775, Throckmorton, TX 76083.

July 1977. Age 32. Bd. cert. M.D. Duke. Int. and res. Columbia Presbyterian Hosp. Group or associate practice in medium community. Daniel C. Dudd, M.D., 789 Kimberly Ct., W., Gaithersburg, MD 20760.

July 1977. Age 28. FLEX. Bd. elig. in July. M.D. from Univ. of Cincinnati. Int. UConn. Res. Akron Gen. Med. Ctr., Ohio. Solo, group or associate practice. Robert A. Cecchino, M.D., 1417-B Timber Trail, Akron, O 44313.

Available now. Age 30. Bd. elig. Group or associate practice in small community. Res. Montefiore Hosp., New York. Barry N. Haicken, M.D., Mt. Horeb Rd., Martinsville, NJ 08836.

July 1977. Age 31. Bd. cert. M.D. Cornell, res. NYU Med. Ctr. Group or associate practice in large or medium community. Peter A. Jarvis, M.D., 5116 Professional Dr., Wichita Falls, TX 76302.

General and Vascular: July 1977. Age 33. Bd. elig. M.D. from Georgetown. Int. Boston City Hosp. Res. Boston Univ. Surg. Serv. Group or associate practice in large or medium community. Contact CSMS-Surg.-JEK.

July 1977. Age 40. FLEX. Res. at Flushing Hosp. and Med. Ctr., NY. Solo, group, associate or institutional practice. Mariano S. Morales, M.D., 11 Bernard St., Port Washington, NY 11050.

Vascular: July 1977. Age 30. Bd. elig. Int. Mt. Sinai Hosp., Florida, res. New Rochelle Hosp. Group or associate practice in medium community. Darayes S. Mobed, M.D., 80 Guion Place, New Rochelle, NY 10801.

Vascular: July 1977. Age 30. Bd. elig. Group or associate practice in medium or small community, but will consider other situations. M.D. from Downstate. Res. at Maine Med. Ctr. Lewis F. Pollak, M.D., 88 Coach Lantern Lane. Scarborough, ME 04074.

July 1977. Age 31. FLEX. Bd. elig. Solo or group practice in medium community. Res. at Illinois Central Community Hosp. Mishah M. Vahidy, M.D., 5050 S. Lakeshore Dr., #710S, Chicago, IL 60615.

July 1977. Age 30. Bd. elig. Res. at St. Joseph's Hosp., New Jersey. Solo, group, associate or institutional practice in large, medium or small community. S. Vallabhaneni, M.D., 88 Mary St., #805, Paterson, NJ 07503.

July 1977. Age 31. Bd. elig. M.D. from Columbia Col. of P&S. Int. from Dartmouth. Presently in active duty. Group or institutional practice in large or medium community. Edward Z. Walworth, M.D., 936 Tall Pine Rd., Mt. Pleasant, SC 29464.

UROLOGY

July 1977. Age 28. Bd. elig. Group or associate practice. Int. from Hershey Med. Ctr., res. Penn. State. Joseph Drago, M.D., 132 S. Landis, Hummelstown, PA 17036.

June 1977. Age 29. Bd. elig. M.D. from Jefferson Med. College. Res. from Henry Ford Hosp., Michigan. Group or associate practice, in large community. Ronald L. Kabler, M.D., 25355 Shiawassee #105, Southfield, MI 48034.

June 1977. Age 33. Nat's Bds. M.D. from SUNY. Int. and res. from Univ. of Vermont. Fellowship at Univ. of Minnesota. Solo, group or associate practice in large or medium community. David H. Kauder, M.D., 4016 Grimes Ave. S., Edina, MN 55416.

June 1977. Age 30. Bd. elig. Interested in Hartford, New Haven or Bridgeport areas. Solo, group or associate practice. M.D. from Univ. of Maryland. Int. from Montefiore Hospital, NY, res. from Univ. of Miami. Julian A. Gordon, M.D., 606 E. Colonia Apts., Cherry Hill, NJ 08802.

July 1977. Age 33. FLEX. Bd. elig. Group or associate practice in large or medium community. M.D. from Georgetown. Int. at Bronx Municipal Hosp. Res. at NY Univ. Med. Ctr. Jeffrey Kosow, M.D., 414 Fireside Lane, Cherry Hill, NJ 08003.

July 1977. Age 34. Bd. elig. M.D. from Duke. Int. at NYU-Bellevue. Res. at John Hopkins. Group or associate practice in large community. Presently on active duty. Arnold M. Kwart, M.D., 820 Bayfield Way #301, Colorado Springs, CO 80906.

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June 1977. Age 31. Bd. elig. M.D. from NJ Col. Int. from Northwestern, Solo, group or associate practice in large or medium community. Steven Ross, M.D., 4469 Chestnut Ridge Rd., Tonawanda, NY 14150.

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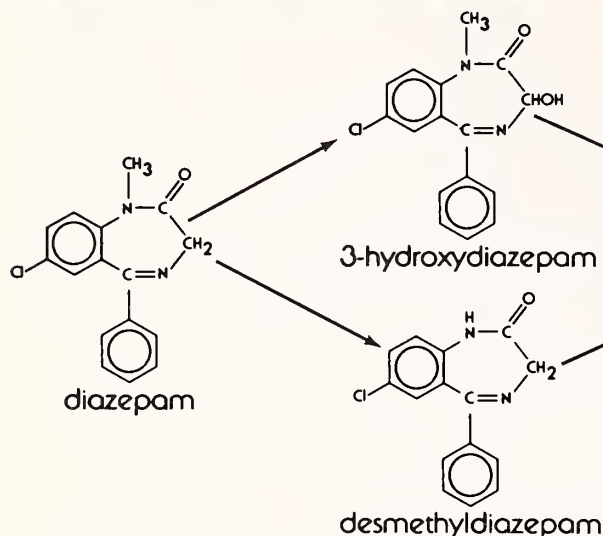
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Adjuvant Treatment of Cancer

II. Breast Carcinoma

(This is the second of a series of articles on the adjuvant treatment of solid tumors.)

Michael V. Viola, M.D. and J. Scott Nystrom, M.D.

Adjuvant chemotherapy for breast carcinoma refers to the administration of cytotoxic chemotherapy for a predetermined length of time commencing immediately after presumed curative surgery. The concept that additional therapy is necessary, even in patients who have had all local disease removed has evolved for a number of reasons. These include: 1) more precise information concerning the natural history of this disease, particularly as related to relevant prognostic factors; 2) evidence that cytotoxic chemicals, particularly when used in combination, can cause regression of recurrent breast cancer, and 3) theoretical considerations emphasizing the advantage of treating small subclinical foci of metastatic disease rather than waiting for systemic disease to become clinically evident.

1) The removal of all local disease in the breast and axilla, either by surgery, radiotherapy or both fails to cure a significant (@45%) number of patients.^{1,2} Routine use of post-operative radiotherapy to regional axillary nodes do not increase cure rates or duration of survival.² It is evident neoplastic cells have disseminated prior to the time of primary surgery in these patients and local measures (be they radical or simple) would be inadequate to effect cure. A number of factors have been elucidated that can predict outcome in this group of patients undergoing "curative" surgery. Poor prognostic signs include spread to regional lymph nodes, large tumor size (>2 cm.), unfavorable histopathology (i.e. undifferentiated nuclear grade, invasion of blood vessels by neoplastic cells, lack of infiltration with lymphocytes, non-medullary cell carcinoma) and lack of sinus histiocytosis in regional lymph nodes.^{1,3,4} A major prognostic factor is the degree of involvement of the regional axillary lymph nodes at the time of surgery. In the absence of lymph node involvement, 20% of patients will suffer a recurrence. When 1-3 nodes are involved, 42% of patients have disease recurrence and 76% of patients will recur when more than 4 nodes are involved.¹ The usefulness of this prognostic indicator is dependent, of course, upon the adequacy of lymph node dissection and the total number of nodes removed. It should be emphasized that local recurrences often herald or occur si-

multaneously with metastatic disease⁴ and once metastatic disease occurs only palliation can be hoped for.

2) A number of cytotoxic drugs will induce a temporary regression of metastatic breast cancer in @20-30% of patients.^{5,6} However, only one complete remission has been well documented in 1600 patients undergoing trial with single drug therapy.⁷ The empirical use of drugs in combination for breast cancer began in the late 1960's⁸ and was finally accepted as standard practice with the advent of Cooper's regimen.⁹ At the present time 5-fluorouracil (F), methotrexate (M), cyclophosphamide (C), vincristine (V), prednisone (P) and adriamycin (A) have been used in various 2-5 drug combinations in both chronic and intermittent administration regimens.¹⁰ The most promising results are in the range of 55-60% response rates, which include a significant number of complete remissions and regressions of bone metastases, which were previously unheard of using single agent cytotoxic chemotherapy. Unfortunately the duration of response is brief (6-8 months) even in the most encouraging series.

3) Both human cancer data and evidence from animal test systems indicate that the response to cytotoxic drugs is inversely proportional to the tumor mass size. Both response rates and survival of patients with sensitive tumors (e.g. choriocarcinoma, Burkitts lymphoma) are greater with localized (early) as compared to disseminated (late) disease.

In animal tumor systems smaller tumor deposits have demonstrated more cells actively dividing (increased growth fraction) and less cells in resting phase than larger tumor deposits.^{11,12} These kinetic characteristics render tumor cells in smaller foci more sensitive to a larger number of chemotherapeutic agents.

In summary, those breast cancer patients who undergo "curative" surgery but who demonstrate any of the poor prognostic signs listed above are at high risk for developing systemic fatal recurrences. Experimental animal tumor data would suggest the most opportune time to treat patients with metastatic cancer is as early as possible (i.e. commencing at the time of surgery).

Results of Adjunctive Chemotherapy Trials

A number of preliminary studies demonstrated equivocal results concerning the usefulness of ad-

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junctive chemotherapy in breast cancer.¹³ The five major studies of significance in this area are summarized in Table 1. The Scandinavian study¹⁴ was a preliminary report which had a poor definition of primary treatment and inadequate documentation of side effects. The results of NSABP III¹⁵ and the study from Milan, Italy¹⁶ must be interpreted cautiously because of a very short mean follow-up period (nine and fourteen months respectively). Nevertheless there are a number of generalizations that can be made from data included in Table 1.

1) The original attempt to use chemotherapy at the time of surgery only, in order to decrease implantation of disseminated viable tumor cells resulting from surgery, had a negligible effect on the future course of the disease.

2) Short term 5-fluorouracil following surgery was of no benefit.

3) The use of more prolonged courses of chemotherapy, particularly with multiple drugs, appeared to decrease the short term recurrence rates.

4) Although the decrease in recurrence rates appears to be more marked in the premenopausal group treated with L-PAM in NSABP III, it has been difficult to correlate this effect with a drug-induced altera-

tion of ovarian function. CMF was equally effective in both pre and postmenopausal women in the Milan study.

5) The more aggressive the chemotherapy schedule used, the more dramatic was the decrease in short term recurrence rates and the more severe the toxic side effects. There were considerable discomforting side effects resulting from treatment in the Milan study.

6) There is limited data at the present time to say with certainty what is the optimum choice of drugs, dosage or schedule to be used as an adjuvant regimen.

There has been no recent report which has influenced the medical treatment of neoplastic diseases to the extent that the study of Bonnadonna et al¹⁶ which advocates prophylactic CMF therapy after radical mastectomy, with the possible exception of DeVita et al¹⁷ report on MOPP therapy for Hodgkin's disease. The Milan study has been referred to as "a work of monumental importance"¹⁸, "greatly exaggerated"¹⁹, "slender results"²⁰ by various reviewers. In fact, the data are quite clear; within the first two years following "curative" mastectomy, systemic CMF chemotherapy decreases the recurrence rate of patients undergoing curative surgery, even those patients in

Table 1
SUMMARY OF MAJOR ADJUNCTIVE CHEMOTHERAPY TRIALS
FOR BREAST CANCER PATIENTS SUBJECTED TO "CURATIVE" SURGERY

<i>Trial</i>	<i>Treatment Groups (# Patients)</i>	<i>Toxicity</i>	<i>Results</i>
Scandinavian (14) 1965-1971	"A"—Surgery or radiotherapy (323) "B"—A + cytoxan 30 mgs/kg i.v. x 6 days, start day of surgery (298)	Not documented	-5% decrease in recurrence rates in "B" group -No difference in survival
NSABP* I (1) 1958-1961	"A"—Radical Mastectomy (406) "B"—A + Thiotepa 0.2 mgs/kg/day i.v. three consecutive days, start day of surgery (414)	"B"—Leukopenia (20%)	-No difference in overall survival and recurrence rates -Survival and recurrence rates significantly improved in premenopausal "B" Group with 4+ nodes involved
NSABP II (1) 1961-1968	"A"—Control—no chemotherapy (207) "B"—5-Fluorouracil 15/mgs/kg i.v. x 5 days, start 7th day post-op (684) "C"—Thiotepa as in NSABP I (274)	"B"—leukopenia (40%)	-5-Fluorouracil of no use -lower recurrence rate in "C" as in NSABP I, except not significant
NSABP III (15) 1972-1974	"A"—Radical Mastectomy (103) "B"—L-phenyl alanine mustard (L-PAM) 15 mgs/kg/day po x 5 days, begin 2-4 wks. post-op., every 6 weeks x 2 years (108)	"B"—nausea & vomiting (30%), leukopenia (60%)	-Recurrence rates significantly decreased in "B" (9.7%) as compared to "A" (22%) -Highly significant in premenopausal group ("A"—30% recurrence, "B"—3% recurrence)
Institute Nazionale (16) Tumori 1973-1976	"A"—Radical Mastectomy (179) "B"—Cytosan 100 mgs/m ² /day po x 14 days Methotrexate 40 mgs/m ² i.v., day 1.8 5-Fluorouracil 600 mgs/m ² i.v., day 1.8 Start 2 wks. post. op., repeat monthly (day 29) x 12 cycles (207)	"B"—nausea (18%) cystitis (27%) alopecia (57%) leukopenia (67%)	-Recurrence rates significantly decreased in "B" (5.3%) as compared to "A" (24%). Statistically significant in all menopausal groups, with and without lymph node involvement

*National Surgical Adjuvant Breast Project

poor prognostic groups. The hesitance for universal and routine acceptance of this regimen is justified on the following grounds:

1) It has not been shown that survival will be prolonged in the drug treatment group. In turn, the fear that recurrent cancer in patients who receive CMF may have a more aggressive, *drug resistant* disease, and results in a shorter survival time from recurrence to death than in the control group has contributed to this lack of widespread acceptance. It is of interest that the one group of patients in the NSABP I study showing an advantage in short term thiotepa did not have a more aggressive form of recurrent disease than the non-drug treatment group.

Unlike a number of other forms of cancer, patients with surgically treated breast cancer are at constant risk of recurrence for @ 15 years.²¹ Therefore, because the force of mortality from this disease is constant and persists for a long period, adequate survival data will be difficult to obtain for a number of years.

2) The side effects of the CMF study (i.e. 10% of patients had alopecia necessitating wigs, 30% had cystitis, 67% had grade I leukopenia (2,500-3,999 leukocytes/mm³), are severe enough that if this regimen is followed as stated, lack of patient compliance may be a major problem.

The carcinogenic potential of these drugs administered in this manner to breast cancer patients is not known.

3) There must be an effort to support the patient and prepare her for the immense disappointment that will occur when many patients receiving this aggressive regimen have disease recurrence.

4) It is still not known if less toxic hormonal manipulations would be as effective as CMF therapy in patients with hormonally sensitive tumors. The lack of effect of prophylactic oophorectomy^{22, 23} in a number of series may have obscured a potentially good response in patients with hormonally sensitive tumors (e.g. those with tumors possessing estrogen binding proteins).

In summary, it is clear that many patients subjected to radical surgery and radiotherapy need systemic therapy for total cure of their disease. The initial promising results manifest by decreased recurrence rates in the first two years following mastectomy using aggressive multiple drug chemotherapy have not been shown to prolong survival, but it appears likely that it will, at least in a subset of the breast cancer population. At the present time, it would seem advisable that patients who have undergone radical mastectomy for cure be followed by medical oncologists for administration of chemotherapy and careful follow-up. It is quite likely that less toxic, equally effective

adjuvant regimens will be developed in the near future to diminish recurrences and possibly prolong survival in this disease.

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Surgical Management of Unstable Angina Pectoris

Rene A. Langou, M.D.

ABSTRACT—Predictors of operative mortality were studied in 124 consecutive patients undergoing coronary artery bypass surgery for unstable angina pectoris. Clinical, hemodynamic, angiographic, anatomic and surgical data were collected on each patient and analyzed to select those factors which could predict operative mortality.

The overall mortality was 4.8% (6/124) for the entire group. Age, failure to respond to medical therapy, chronic hypertension, extent of coronary artery disease, minimal elevation of cardiac enzyme before surgery and prolonged cardiopulmonary bypass time, all significantly affected operative mortality.

Introduction

A variety of terms are used to define a group of patients who present with an altered angina pectoris pattern and have a high risk of myocardial infarction and its complications. Terms such as "impending coronary occlusion,"^{1,2} "unstable angina,"³ "intermediate coronary syndrome,"⁴ "preinfarction angina,"⁵ "impending myocardial infarction,"⁶ "coronary failure,"⁷ "coronary insufficiency,"⁸ "crescendo angina,"⁹ and "accelerated angina"¹⁰ are used to describe this entity.

With the availability of direct myocardial revascularization (saphenous vein or mammary artery-coronary artery bypass grafts) in recent years, enthusiasm for surgical intervention in this high risk group of patients has resulted in the widespread use of this therapeutic procedure.^{11,14} The variability in definition and lack of general agreement as to what constitutes unstable angina, however, has made assessment of surgical therapy quite difficult. This study was therefore undertaken to: 1) precisely define a high-risk sub-group of patients employing a rigorous criteria for unstable angina; 2) evaluate the risk of aggressive diagnostic procedures and surgical therapy and 3) identify a group of patients who may have a higher risk than the usual patient with unstable angina.

Material and Methods

One hundred twenty-four consecutive patients underwent cardiac catheterization and coronary artery bypass surgery for unstable angina pectoris at the Yale-New Haven Hospital from January 1974 to June 1975.

The criteria for diagnosis of unstable angina pectoris were the following; 1) prolonged typical angina pain (longer than 20 minutes); 2) typical angina pain occurring at rest; 3) pain not completely relieved by nitroglycerin, 4) failure to document an acute myocardial infarction by serial electrocardiograms and serial enzyme determinations.

After admission to the coronary care unit, all 124 patients were treated with maximal medical therapy including long and short acting nitrates (Isordil sublingually every 3 hours and Nitroglycerin as needed), large doses of propranolol and absolute bed rest.

Fifty-three patients responded to medical therapy within 48 hours after admission to the hospital. All of these patients were free of pain at rest but remained symptomatic with minimal exertion. Seventy-one patients continued to have severe resting angina for more than 48 hours after admission to the hospital despite medical therapy. An intra-aortic balloon pump was placed in 26 patients in this latter group to stabilize their angina symptoms prior to cardiac catheterization and surgery. Electrocardiograms were obtained at least daily. In the majority of patients, however, multiple tracings were taken during the day, especially during angina attacks. Cardiac enzymes (SGOT, CPK, and LDT) determinations were obtained in each patient daily for up to 3 days postoperatively and in some cases for up to 7 days after surgery. Electrocardiographic and enzymatic criteria for myocardial infarction were derived from the Minnesota code¹⁵ and Sobel and Shell criteria¹⁶ respectively.

Cardiac catheterization was performed an average of 10 days after admission in the group that responded to medical therapy, and after 5 days in the group that did not respond. Diagnostic cardiac catheterization consisted of pressure measurements, cardiac output determination, single plane left ventriculography and selective coronary arteriography. Coronary artery lesions of greater than 70% obstruction were considered as significant. Coronary artery disease was classified as one, two or three-vessel disease. Left main coronary artery disease was considered equivalent to disease of the proximal left anterior descending and proximal circumflex arteries. Coronary artery bypass grafts were performed within one week after cardiac catheterization in the majority of our patients. Surgery on patients in whom an intra-aortic balloon pump was placed was, however, usually done within two days following cardiac catheterization. The intra-aortic balloon pump was

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removed in all 26 patients within 48 hours after surgery. Operative mortality was considered to be either in-hospital mortality or death up to 6 weeks after surgery.

Statistical analysis was performed using contingency table Chi-Square to examine each of the study factors. When information on some preoperative clinical characteristic of an individual patient was not available, the patient was removed from the analysis for that variable.

Demographic Characteristic

The mean age of these 124 patients was 55 years (range: 37 to 76); 77% were male; and 23% were female. Peripheral vascular disease was present in 45% of the patients, diabetes mellitus in 17%, lipid abnormality in 33%, family history of ischemic heart disease in 68%, systemic hypertension in 30%, obesity in 58%, old myocardial infarction in 52%, and congestive heart failure in 16% of the patients. Twelve per cent of the patient population were not on propranolol, 28% received less than 160 mg, and 60% were given more than 160 mg of propranolol daily.

Cardiac enlargement by chest x-ray (CT Ratio > 50%) was present in 20%, abnormal left ventricular end-diastolic pressure (> 12 mm Hg) in 43%, abnormal ejection fraction (< 60%) in 36%, and mild to moderate mitral regurgitation in 14% of the 124 patients.

The extent of coronary artery disease in these 124 patients was as follows: 12% had single vessel disease, 26% double vessel disease, 62% triple vessel disease and 13% left main coronary artery involvement.

Results

Coronary artery bypass surgery in this group of patients with well documented unstable angina pectoris carried an overall morbidity of 4.8% (6/124). Several factors appeared to affect operative mortality including age, in-hospital medical treatment, chronic systemic hypertension, extent of coronary artery disease, left ventricular end-diastolic pressure, minimal elevation of cardiac enzymes and duration of cardiopulmonary bypass pump (see Table 1).

The thirty-nine patients older than 60 years of age had an operative mortality of 10% (4/39), while younger patients had a significantly lower mortality, 2% (2/85). The 53 patients who responded favorably to medical therapy did not have mortality while the 71 patients who failed to respond to medical therapy had a significantly higher mortality (8.5%, 6/71). Patients with documented chronic hypertension had a higher mortality than patients without hypertension (13.5% vs 1.2%) and similarly patients with three vessel coronary artery disease had a significantly higher mortality than those with single or double coronary artery

Table 1
OPERATIVE MORTALITY OF 124 PATIENTS WITH UNSTABLE
ANGINA PECTORIS BY VARIOUS CLINICAL FACTORS

	Number of Patients		Mortality %	
	With Factor	Without Factor	With Factor	Without Factor
Age > 60 years	39	85	10%	2%
Responder to medical therapy	53	71	0%	8.5%
Hypertension	37	87	13.5%	1.2%
Three vessel disease	77	47	7.8%	0%
Left main coronary artery disease	16	108	25%	1.9%
LVEDP * > 12 mm Hg	53	71	7.6%	2.8%
Elevation of LDH**, SGOT***, and CPK****	27	97	14.8%	2%
CPB Time > 120 min †	11	113	55%	0%

* LVEDP: Left ventricular end-diastolic pressure;
** LDH: Serum lactate dehydrogenase;
*** SGOT: Serum glutamin oxalic transaminase;
**** CPK: Creatine phosphokinase;
† CPB Time: Cardiopulmonary bypass time.

disease (7.8% vs 0%). There was even higher mortality in patients with left main coronary artery disease when compared to those with triple vessel disease (25% vs 7.8%) and furthermore, these patients did not respond to medical therapy continuing to have an unstable angina pattern despite maximal medical therapy.

During chest pain, ST segment deviation was observed in only 75% of the patients with left main coronary artery disease. This figure is however, significantly higher than in the overall population (35%). The operative mortality of patients with ST segment deviation during angina pain and those without ST segment change was not significantly different. Patients with LVEDP greater than 12 mm had a mortality of 7.6% (4/53), which declined to 2.8% (2/71) in patients with normal LVEDP.

The analysis of daily LDH, SGOT and CPK enzyme determinations revealed that 27 patients had minimal elevation of at least one enzyme but this abnormality was not associated with the typical pattern of enzyme rise observed in acute myocardial infarction. Of these 27 patients, 4 died after surgery yielding an operative mortality of 14.8%; while 97 patients who did not show the enzymatic abnormalities had only a 2% mortality (2/97).

The duration of cardiopulmonary bypass pump played a very important role in operative mortality. When the cardiopulmonary bypass pump time was longer than 120 minutes, the operative mortality was

very high, 55% (6/11), while shorter pump time was not associated with mortality (0/113). The excessive pump time in all patients who were bypassed for longer than 120 minutes could have been predicted on the basis of their coronary arteriograms. These patients had severe diffuse distal disease in the coronary tree and therefore the distal anastomoses of the coronary grafts were extremely difficult to perform, thus increasing the pump time to undesirable levels.

Discussion

Patients who were hospitalized for unstable angina pectoris were included in this study only if they met rigid diagnostic criteria, and underwent cardiac catheterization followed by aorto-coronary bypass grafting during the same admission. We estimate that the number of patients excluded because they failed to meet these criteria was at least as large as the number of patients included in the study. Therefore in comparison to some other studies in which unstable angina has been more broadly defined, our patients constitute a relatively homogenous clinical group possessing an especially high risk of myocardial infarction or death.¹⁸

The overall surgical mortality of 4.8% is comparable to that reported from several recent surgical studies¹⁸⁻²¹ which ranged from 2% to 22%. It must be noted, however, that most of the authors considered operative mortality as death occurring within 4 weeks rather than 6 weeks, as was the case in our study.

Operative mortality was significantly higher in patients older than 60 years of age. The prevalence of triple vessel disease was, however, also significantly higher in this older population 69% (7/39) as compared to the group whose age was below 60 years 59% (50/85). Triple vessel disease constituted a very powerful factor influencing operative mortality. Therefore, age alone could not be used to predict operative mortality in this series of patients with angina pectoris. It appears clear that age significantly influenced operative mortality while added to other important risk factors such as triple vessel disease. For example, the operative mortality of patients with triple vessel disease and age below 60 years was 4% (2/50) while patients with triple vessel disease and age over 60 years of age was 14.8% (4/27).

The patient's response to medical therapy appears to be very important in reducing the operative mortality in this group of patients. We had no mortality in those patients in whom we obtained complete relief of their resting angina by the use of β -adrenergic blocking therapy plus long and short-acting nitrates. Propranolol therapy was used very aggressively and the doses were gradually increased until complete relief of pain was obtained, the resting heart rate was 50-55 per minute, or there were clinical evidences of heart fail-

ure which could not be controlled with standard treatment of congestive heart failure. Seventy-one patients continued to have chest pain despite maximal medical therapy, and in 26 patients an intra-aortic balloon pump was placed to stabilize their symptoms. Every patient who received an IABP experienced immediate relief from pain after activation of the balloon. Patients with systemic hypertension had a higher operative mortality than those without, suggesting that the hypertrophic left ventricle does not tolerate periods of myocardial ischemia.

Patients with severe atherosclerotic disease of their coronary arteries presenting with a pattern of unstable angina had a significantly high mortality as reflected by the operative mortality of patients with triple vessel disease or left main coronary artery disease. We documented that left main coronary artery narrowing constituted the most powerful predictor of operative mortality (Table 1).

The patient with left main coronary artery disease was characterized by the failure to respond to optimal medical therapy, the presence of ST segment changes during chest pain and minimal elevation of serial LDH, SGOT and CPK enzyme determinations.

Left ventricular end-diastolic pressure appeared to influence the overall operative mortality of the patients. However, left ventricular end-diastolic pressure could be elevated as a result of the β -adrenergic blocking therapy instituted in all of these patients rather than due to intrinsic lack of compliance of the left ventricle secondary to actual ischemia or previous myocardial damage. The analysis of serial daily cardiac enzyme determinations while patients were in the coronary care unit revealed 27 patients (22%) who minimally elevated their enzymes (less than twofold normal values) during the clinical course before surgery. These patients had a significantly higher operative mortality (14.8%) than those patients who did not elevate enzymes (2%). This observation suggests that these patients did have some degree of myocardial necrosis but it was either so minimal or so diffuse that it was undetectable on the electrocardiogram.

The cardiopulmonary bypass duration played an extremely important role in determining operative mortality. The duration of the cardiopulmonary bypass was, however, in direct relationship to the number of grafts that had to be performed, and the anatomical condition of the arteries receiving grafts. We had 11 patients in whom the cardiopulmonary bypass time was longer than 120 minutes. All of these patients had triple vessel disease and 4 of them had left main coronary artery disease. Coronary arteriography revealed diffuse distal disease in all the arteries where grafts were to be placed causing significant technical problems at the time of the distal anastomo-

sis. This problem could be predicted preoperatively on the basis of arteriography.

Several clinical implications can be derived from this study: 1) It appears that the ideal time for surgical intervention in patients with unstable angina is after their angina pain is controlled with medical therapy. 2) The introduction of intra-aortic balloon counterpulsator appears to be desirable because symptoms are controlled immediately, and it may also reduce the cardiac catheterization morbidity and mortality. Furthermore, intra-aortic balloon assistance makes easier the withdrawal of propranolol in the preoperative period. 3) Patients older than 60 years of age with hypertension and with three-vessel disease are a high risk for operative mortality when they undergo coronary artery bypass surgery for unstable angina pectoris.

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Ambulatory Cardiac Monitoring

Edwin Hankin, M.D.

ABSTRACT—Ambulatory electrocardiography appears to have more than fulfilled Dr. Holter's original hopes. Practical equipment is now widely available at reasonable cost levels. It must be regarded as the most satisfactory method of detection of arrhythmias and transient conduction abnormalities. It is of considerable value in the assessment of chest pain, transient neurologic symptoms and in the detection and management of ischemic heart disease. It may be finally, the earliest and most practical method of detecting the coronary prone patient, especially those subject to the risk of sudden death.

Twenty-four hour electrocardiographic recording of ambulatory patients is a new and valuable addition to the medical armamentarium. We can now document arrhythmias and identify ischemic episodes in the outpatient population. New uses in the detection and therapy of heart disease seem to be found almost daily for this theoretically simple yet quite ingenious device.

On August 1, 1949 Norman J. Holter of Helena, Montana presented a paper entitled "Remote Recordings of Physiological Data by Radio" to the annual meeting of the Montana Medical Association which was subsequently published in the *Rocky Mountain Medical Journal* in September of 1949.^{1,2} Holter and his colleagues had been working towards extending the usefulness of physiological recordings by use of electronic techniques which would allow the subject freedom of activity during the performance of such measurements. The early devices consisted of an 80 lb. backpack worn by the patient. Following the development of the transistor, miniaturization has been possible resulting in the small, lightweight commercial units now available.

Enthusiasm for the concept of ambulatory monitoring grew out of information gleaned during the monitoring of patients in Coronary Care Units. Continuous monitoring of these patients provided recognition of the importance of cardiac arrhythmias, and it was apparent that upon leaving the hospital many patients, subject to a vast spectrum of changes of electrocardiographic rhythms, patterns and conduction defects were not available for study and therapy. The last decade has seen a significant increase in the use of these recording devices concomitant with advances in the sophistication of the technology itself.

Equipment

Present techniques permit 24-hour recording of a two channel electrocardiographic signal, usually a modified V₅ and V₁. This is accomplished by a small camera-sized tape recorder carried by the patient, which can weigh as little as one and one half pounds and easily fit into an inside coat pocket. The newest models³ are equipped with digital clock displays coupled with patient activated event markers providing for five-second accuracy of time-event-symptom correlation.

The second component of this system is a playback unit which scans by superimposition of QRS complexes at 30 to 120 times real time, therefore, a 24-hour tape can be scanned in some 12 minutes. Automatic scanning devices⁴ define ST segment and T wave displacement and a continuous histogram of the number of ventricular and supraventricular beats per unit of time provided. A digital event timer relates the electrocardiogram to a patient's diary. In the diary the patient records ongoing 24-hour activities as well as symptomatology for correlation with electrocardiographic changes. Instantaneous ability to change from superimposed high speed playback to real time display and print-out provides easy access to electrocardiographic data for the study of contour or rhythm changes as well as for a permanent record.

Commercial systems currently available vary in recording techniques, operation and capability, but retain the concept of highspeed playback and display of recorded data, with the ability to sample desired portions of the electrocardiogram at real-time rates.⁵ The use of newer multichannel recording systems allows for better separation of ventricular and supraventricular beats with aberrancy.

Clinical Applications

The major usefulness of ambulatory electrocardiography is in detection and characterization of cardiac arrhythmias. In normal subjects, arrhythmias on ambulatory electrocardiograms appear to be infrequent.⁶ The frequency of cardiac arrhythmias increases significantly with age, presumably on the basis of acquired ischemic heart disease. Hinkle et al⁷ found supraventricular premature contractions and other supraventricular dysrhythmias in 76 percent of a group of 302 actively employed American men of median age 55 years old during a six-hour period of ordinary activity. These supraventricular dysrhythmias were not associated with subsequent death from coronary heart disease. Ventricular premature contractions and complex ventricular dysrhythmias were found in 62.2

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percent of the recordings. These were significantly associated with the presence of coronary heart disease at the time of the examination. They were also associated with an enhanced risk of subsequent death from coronary heart disease.

These findings suggest that asymptomatic dysrhythmias and disorders of cardiac conduction are common in the middle aged and older population. The evidence is consistent with the hypothesis that ventricular premature contractions are manifestations of underlying coronary heart disease; and that their presence is associated with an increased risk of subsequent sudden death from coronary heart disease.

I. Coronary Heart Disease

A. Arrhythmia Identification

Extensive experience in the Coronary Care Unit has helped to define ventricular ectopic activity as a harbinger of sudden death in acute coronary disease. Ambulatory monitoring has allowed us to extend these observations to those patients with documented coronary artery disease who have not suffered myocardial damage (i.e. angina pectoris) as well as to the post myocardial infarction state.

In an effort to further identify those patients with coronary heart disease who were asymptomatic but subject to significant ventricular ectopic activity, both exercise stress testing and ambulatory monitoring have been employed. Recent literature document the greater efficacy of 24-hour monitoring as a means of identifying ventricular ectopic activity in patients with coronary heart disease. Ryan and his colleagues⁸ studied 100 unselected patients with coronary heart disease using both maximal exercise testing and 24-hour monitoring. The arrhythmia was noted with exercise in 56 patients and with monitoring in 88. Repetitive forms such as couplets and ventricular tachycardia were found to be twice as frequent (40 versus 20) with monitoring than with exercise. Since VPB's appear to be random and sporadic events, the duration of monitoring is a decisive factor in determining their prevalence;⁹ for example, in the same patient with coronary heart disease, a standard ECG equivalent to less than one minute of monitoring will demonstrate VPB's in 10 percent. When the monitor period is three minutes, about 15 percent show extrasystoles. The yield from 12 hours of monitoring is 60 percent, but when the period of surveillance for arrhythmias is increased to 24 hours, 85 to 90 percent show some VPB's.

Ambulatory monitoring allows the further characterization of the premature beat with reference to the degree of prematurity, configuration of QRS morphology, multiformity, site of origin, frequency, pattern of repetitive occurrence, sequencing, diurnal distribution and other characteristics. Lown and his

colleagues were among the first to suggest classification of ventricular premature beats. Eighty-five percent of patients with stable coronary disease have occasional VPB's. Certain characteristics of ventricular premature beats are more closely related to evidence of coronary heart disease as well as to increased incidence of sudden death.¹⁰ There are many grading systems, however, all agree in ascribing greater importance to increased frequency (greater than 30 per hour), multiformity, R on T phenomena, and couplet sequencing.

This recent elucidation of the importance of ventricular ectopic activity and its further characterization in coronary heart disease has been the focus of several studies relating to the post-myocardial infarction state. A comprehensive investigation of this question was undertaken within the framework of the ongoing coronary drug project.¹¹ Among 2,035 survivors of myocardial infarction, 234 (11.5 percent) had one or more VPB's in their resting base-line ECG. During the three year follow-up period, VPB's were associated with excess risk of death including sudden death. Mortality was nearly twice as great among those with any VPB's (21.7 percent) as compared to those with none (11.4%). Excess long-term risk of death including sudden death, was associated with the frequency of VPB, with VPB in pairs or runs, and with early-cycle VPB.

Attempting to extend the usefulness of this monitoring technique and to determine the prognostic significance of ventricular arrhythmias persisting during the in-hospital ambulatory phase of acute myocardial infarction, Vismara et al¹² studied 64 patients with acute myocardial infarction. Ten-hour Holter monitoring was performed an average of 11 days after discharge from the Coronary Care Unit. In a follow-up period of 25.8 months, there were no deaths among 15 patients who showed only rare VPB's; by contrast, there were eight deaths among 27 with advanced grades of VPB's.

Ambulatory monitoring of patients with coronary artery disease can, therefore, help to detect arrhythmias which may identify those patients who are at high risk for sudden death. Additional monitoring during the post infarction period may be of aid in advising those patients with reference to activity levels, return to work, and perhaps provide some insight into the efficacy of antiarrhythmic drugs. (Fig. 1,2)

B. Detection of Ischemic Changes

With recent improvements in technology, Holter monitoring has been recommended for detection of ST and T wave changes in patients with known or suspected coronary disease.^{13, 14} Stern and colleagues¹⁴ evaluated 50 patients with precordial pain by 24-hour ambulatory ECG monitoring during normal every-

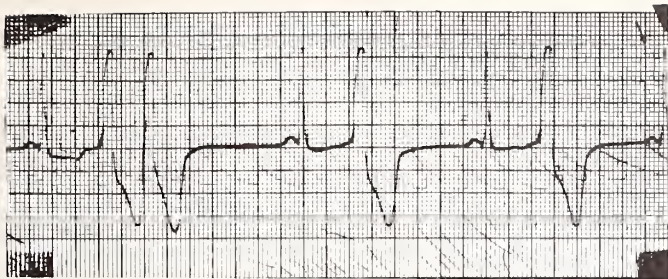
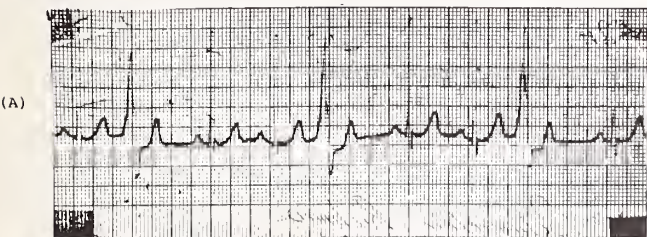


Figure 1

F.K., a 42 year old asymptomatic male 5 months post myocardial infarction. Note significant ventricular ectopic activity with couplet sequencing.



(A)

(A) and (B). Significant ventricular ectopic activity including a run of self-limited ventricular tachycardia at relatively slow resting heart rates.

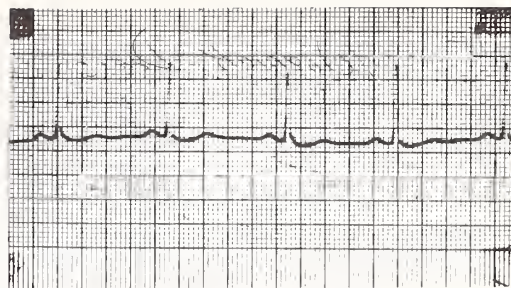


(C). Complete disappearance of all ventricular premature activity with increased heart rate while patient did his morning exercises.

Figure 2
R.S., 32 year old male athlete who noted palpitations only at rest.

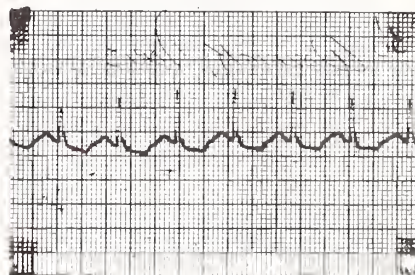
day activities and performed subsequent coronary arteriography. Dynamic ST-T wave changes on monitoring were accompanied in 28 out of 32 patients by severe and in one patient, by moderate pathology (91 percent sensitivity of test), and in only three patients were negative coronary arteriograms found (9% false positives). Ambulatory electrocardiography is particularly useful in the evaluation of ST segment changes occurring on the electrocardiogram when chest pain occurs without relation to exercise, such as emotionally induced, nocturnal, or Prinzmetal angina episodes. (Fig. 3)

(A)



(A). Base line recording

(B)



(B). Recorded during a "diary-documented" episode of chest pain. Note the significant ST-T changes compatible with a "positive" stress test response.

Figure 3

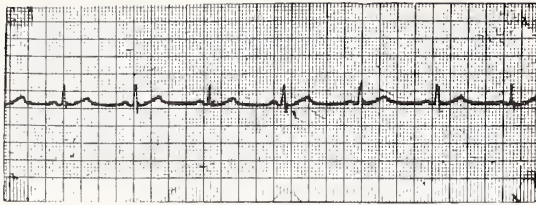
D.W., 48 year old female who complained of non-effort related chest pain.

II. Transient Cerebral Ischemia Due To Arrhythmia

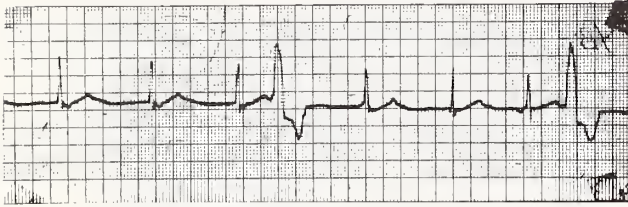
Both atrial and ventricular arrhythmias may precipitously decrease cardiac output, systemic blood pressure, and peripheral arterial blood flow. Normal subjects may tolerate arrhythmias without experiencing symptoms of cerebral ischemia. However, patients with cerebral artery narrowing may manifest either diffuse or focal cerebral vascular insufficiency. Some patients with transient cardiac arrhythmias are unaware of them; therefore, an unsuspected cardiac arrhythmia must be included in the differential diagnosis of episodic cerebral vascular insufficiency.

In 39 patients with symptoms of cerebral ischemia, Walter et al¹⁶ documented ten patients with dysrhythmias on ambulatory monitoring. Antiarrhythmic therapy produced excellent results in five and fair results in three patients. Tzivoni and Stern¹⁷ evaluated 110 patients who were referred to their clinic because of unexplained spells of dizziness, syncope, or vague cerebral symptoms. Twenty-four hour ECG monitoring revealed significant etiologic arrhythmias in 12 (11%) whose symptoms were subsequently relieved by implantation of a permanent pacemaker.

Sinus node abnormalities and atrial ventricular block may produce symptoms of cerebral vascular insufficiency (i.e., dizziness, lightheadedness, syncope, etc.). It is therefore suggested¹⁶ that every patient with intermittent symptoms suggesting cerebrovascular insufficiency should be studied by Holter electrocardiography in order to rule out the presence of an intermittent cardiac arrhythmia or conduction abnormality. (Fig. 4)



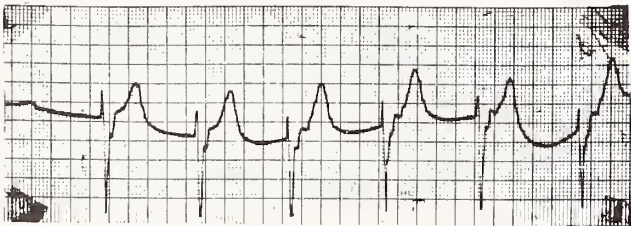
(A). Regular sinus rhythm at beginning of recording.



(B). Nodal rhythm with ventricular escape beats.



(C). Nodal rhythm with second degree block (Wenckebach).



(D). Episode of idio-ventricular rhythm following upon a slow nodal rate.

Figure 4

N.S., 62 year old hypertensive female with a normal 12-lead resting electrocardiogram complaining of "dizziness and falling-out" spells (strips not continuous however obtained during one 24 hour recording).

III. Wolff-Parkinson-White Syndrome

The clinical course of patients with WPW syndrome with tachyarrhythmias may be variable. The onset of episodes may occur at any age, and the course may be one of recurrent tachyarrhythmias with intervening periods of freedom from complaint. Detection of the arrhythmia may be difficult since the problem often ceases by the time that medical attention is obtained. Preventive therapy is therefore often based upon the patient's history and many times palpitations are unrelated to episodes of true arrhythmia.^{18, 19}

Holter monitoring in WPW syndrome permits confirmation that symptoms are being induced by arrhythmias which would eliminate unnecessary antiarrhythmic therapy. Ambulatory monitoring can also be used to confirm the diagnosis of pre-excitation when it occurs intermittently.

IV. Idiopathic Hypertrophic Subaortic Stenosis

Patients with IHSS have palpitations and syncope and are at risk of sudden death. These clinical findings may result from arrhythmias rather than left ventricular outflow obstruction. Ambulatory electrocardiographic monitoring was performed in 27 patients with documented IHSS.²⁰ Premature atrial contractions were recorded in 96 percent of patients and VPB's were recorded in 89 percent (24 out of 27). Ventricular tachycardia was documented in 4 patients (7%). Patients with idiopathic hypertrophic subaortic stenosis or asymmetric septal hypertrophy who complain of unexplained syncope, palpitation, or episodes of dizziness are candidates for ambulatory monitoring.

V. Pacemaker Problems

The reappearance of symptoms that prompted the initial use of a pacemaker often signal pacemaker malfunction. In one study of 48 patients with suspected pacemaker malfunction, routine clinical examinations, standard electrocardiography, and pacemaker evaluation clinics failed to detect pacemaker malfunction in 9 of these 48 patients (18%), which were discovered on Holter monitoring. Since most pacemaker clinics simply derive information about battery integrity instances of intermittent pacemaker malfunction or pacemaker-induced arrhythmias may not be detected by the standard pacemaker clinic examination.

VI. Evaluation of Antiarrhythmia Therapy

Ambulatory monitoring has proven that rhythm disturbances are frequent occurrences during normal daily activities in both the cardiac and noncardiac states. Antiarrhythmic agents currently employed involve inconvenience, expense, and certainly risk of iatrogenic disease. Despite these considerations, arrhythmias frequently cause serious symptoms or appear to have such ominous prognoses that antiarrhythmic therapy is justified by clinical judgment.

Ambulatory monitoring provides the physician with a tool by which he can assess the significance of the arrhythmia, monitor therapeutic efficacy and by periodic re-monitoring continue to confirm continuing beneficial results of this therapy.

VII. Research

The research applications of ambulatory electrocardiographic recordings are numerous. Evaluation of the effects of numerous activities upon the normal and cardiac patient will hopefully provide greater insights into cardiac physiology and clues to more effective therapy.

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Unilateral Pharyngeal Paresis

Clarence T. Sasaki, M.D. and John A. Kirchner, M.D.

ABSTRACT—Distinguishing hypopharyngeal neoplasms from unilateral pharyngeal paresis may be difficult because of similar physical and radiographic findings. The pitfalls of differential diagnosis are illustrated by case presentations and are discussed according to history, physical, and radiographic findings. Careful cinefluorography allows the best opportunity in differential diagnosis by identifying the paretic side as the pyriform sinus that maximally fills on routine barium swallow. In this regard one should appreciate that the contralateral tonic side may fail to fill completely thus mimicking the presence of a tumor mass within it.

INDEX TERMS

Pharyngeal paresis, Barium swallow

Introduction

Swallowing difficulty is a relatively common complaint caused by a surprising variety of disorders. Within the pharynx alone, one may encounter obstructive neoplasms producing pain, aspiration, and dysphagia. Narrowing of the lumen by deep neck abscesses may interfere with food passage. Prominent

cervical exostoses also may produce dysphagia. Similar complaints may result from pulsion diverticulum, elongated styloid process, cricopharyngeal hypertonicity, and hypopharyngeal mucosal webs.

Although most of these disorders are readily revealed by careful history taking and physical examination, others require skillful radiologic and endoscopic investigation. Nevertheless one cause of swallowing difficulty continues to perplex the diagnostician. In 1958 Kirchner¹ carefully described the radiographic appearance of unilateral pharyngoplegia as distinct from that produced by a hypopharyngeal neoplasm. In each case the cause of pharyngeal paresis was attributed to bulbar lesions, although the exact etiologies remained unknown.

However, despite such careful radiologic description years ago, the occasional patient is still referred to the laryngologist with the diagnosis of "carcinoma of the pyriform sinus" when careful review of the barium swallow film instead reveals an unrecognized contralateral pharyngoplegia.

In this regard we shall describe three patients referred to laryngologists at the Yale-New Haven Medical Center within the past three years for treatment of suspected "carcinoma of the hypopharynx". Instead contralateral pharyngeal paresis was demonstrated to be the cause of swallowing difficulty in each instance.

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Furthermore continued investigation produced evidence of intracranial neoplasms as the cause of pharyngoplegia. These experiences have necessarily prompted us to restate the unique radiographic appearance of unilateral pharyngeal paresis in the production of dysphagia.

Case Histories

1. AD, a 63-year-old laborer, developed progressive swallowing difficulty and occasional aspiration. He had been intermittently hoarse for several years, although experienced no shortness of breath. A barium swallow (Fig 1) revealed a filling defect of the



Figure 1
"Filling defect" of right hypopharynx

right hypopharynx suggesting a neoplasm. After a negative esophagoscopy he was transferred to the Yale-New Haven Medical Center for repeat endoscopic evaluation. Mirror inspection revealed saliva pooled in the left pyriform sinus, and an immobile left vocal cord was observed in the paramedian position. The palate appeared asymmetric and tongue protruded to the left. Repeat barium swallow now revealed left hemiatrophy of the tongue, a dilated left pyriform sinus, and slightly abducted left vocal cord causing aspiration of contrast medium. (Figure 2) Internal carotid angiography revealed a tumor blush in the left posterior cranial fossa. (Figure 3) Further investigation revealed this to be metastatic adenocarcinoma of the prostate.

2. PM, a 65-year-old female patient, developed swallowing difficulty. She complained that she occasionally choked on liquids. Her voice had become progressively hoarse. Incidentally she had suddenly lost the hearing in her left ear, but was never unsteady. She was referred to the section of Otolaryngology for evaluation of a "right pharyngeal tumor" seen on barium swallow. (Figure 4) Mirror examination revealed saliva puddled in the left pyriform sinus and an immobile left vocal cord in the paramedian position. The pharyngeal mucosa appeared intact and no tumor could be seen above the larynx. Reinterpretation of the contrast esophagram now supported abnormal dilatation of the left pyriform sinus consistent with left pharyngeal paresis. Repeat endoscopy confirmed the absence of a primary pharyngeal tumor. Skull X-rays revealed a calcified mass in the left cerebello-pontine angle which proved to be a meningioma (Figure 5).



Figure 2
Dilated left pyriform sinus



Figure 3
Tumor blush in left posterior fossa

3. LB, a 63-year-old carpenter, received a barium swallow because of progressive difficulty swallowing. He had been hoarse for years and had undergone several mastoid operations for bilateral chronic otitis media. He was referred to us for further evaluation when several previous endoscopic procedures failed to demonstrate a "throat tumor" suggested by pharyngeal asymmetry apparent on contrast esophagram. (Figure 6) Mirror examination revealed an immobile left vocal cord. Meanwhile because of continued left ear suppuration the patient underwent a revision left mastoidectomy

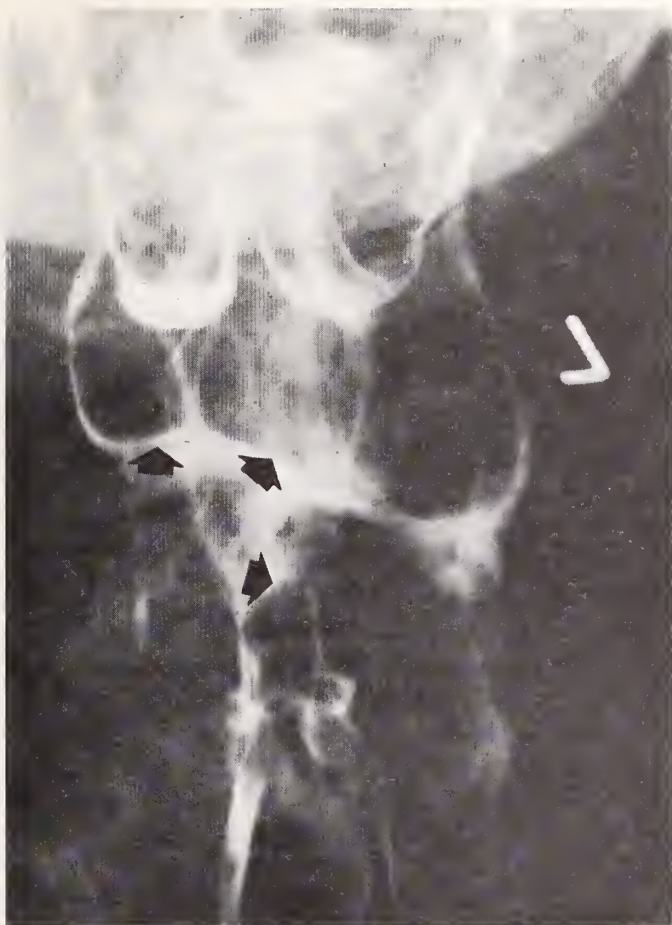


Figure 4
"Tumor" of the right pharyngeal wall



Figure 5
Calcified tumor mass in left posterior fossa

during which 5 units of blood were lost due to uncontrolled hemorrhage. Post-operative carotid angiogram confirmed a glomus jugulare tumor replacing much of the left temporal bone. (Figure 7) Review of the original esophagram in light of these events now supported a dilated atonic left pyriform sinus producing the appearance of a "mass" or "filling defect" on the normally tonic side which did not completely fill.



Figure 6
"Tumor" of the right pharyngeal wall

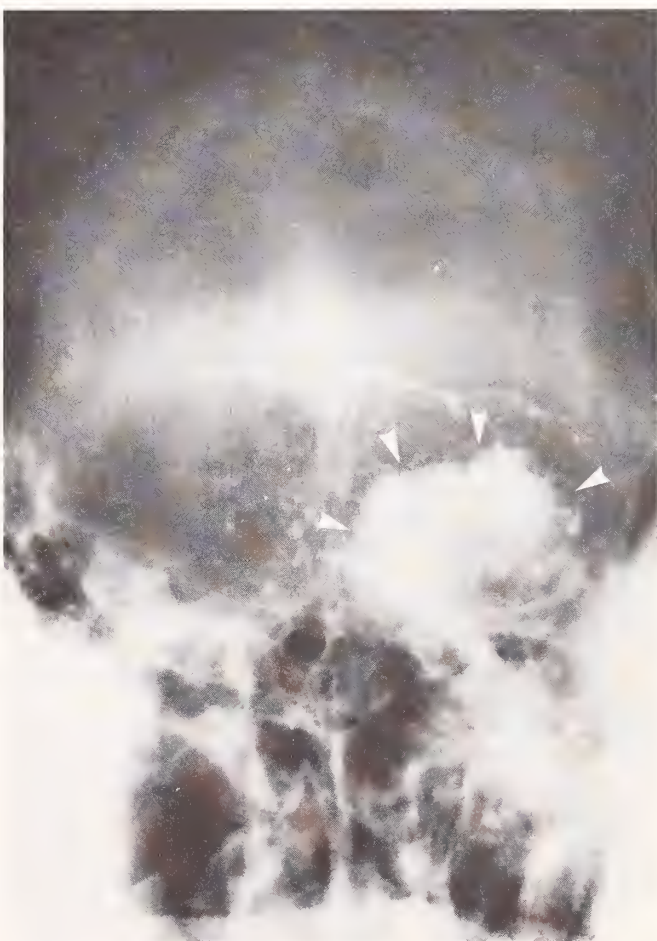


Figure 7
Glomus jugulare tumor demonstrated by angiography

Discussion

Unilateral pharyngoplegia is occasionally difficult to distinguish from hypopharyngeal neoplasm. Symptoms, physical and radiologic findings share certain similarities that may perplex the inexperienced physician.

In carcinoma of the hypopharynx, difficulty swallowing is gradually progressive, the patient experiencing more difficulty with solids than liquids. Conversely in pharyngeal paresis the patient generally tolerates solids better than liquids, fluids having a greater tendency to pool in the pyriform sinus and spill over the aryepiglottic folds to cause aspiration. In either case the patient's description of dysphagia is nonspecific. Hoarseness may accompany either diagnosis. Vocal cord immobility may result from hypopharyngeal tumors that infiltrate the intrinsic laryngeal muscles to produce cord fixation.^{2,3} On the other hand, infranuclear vagus interruption may produce cord paralysis rather than fixation. High vagus involvement above the nodose ganglion is said to produce cord paralysis in the paramedian position,⁴ a glottic configuration predisposing to recurrent aspiration.

On physical examination neck palpation may reveal shift of the trachea caused by the mass effect of tumor compression. However, tracheal shift may also be found in pharyngoplegia caused by the traction of the normal constrictors unopposed by the paretic side. Tracheal shift by itself therefore is nondiagnostic.

Mirror examination may be uninformative if no obvious mucosal neoplasm is seen. A motionless vocal cord may represent either tumor fixation or paralysis. Furthermore tumor edema of the pyriform sinus may be confused with redundant mucosa caused by relaxation of the atonic constrictor muscles. Careful neurologic examination may provide the only revealing information for differential diagnosis when more

cranial nerves than the pharyngeal branch of the vagus happens to be involved by high vagus interruption.

The "filling defect" on a routine barium swallow film may be deceptive since this may represent incomplete filling of the pyriform sinus on the uninvolved side mimicking a mass-lesion when this is compared to maximal filling obtained on the paretic side. Of course, particles of food matter should be removed from the paretic sinus since they may confuse diagnosis further. Simultaneous maximum filling of both pyriform sinuses is essential to the interpretation of the contrast study and may best be achieved by placing the patient supine during deglutition of the barium bolus.⁵ This sufficiently slows the passage of barium to allow simultaneous, maximum filling of both pyriform fossae facilitating radiologic comparison. Cinefluoroscopic observation greatly enhances the ability to diagnose the paretic pharynx.⁶ With the mucosa coated by contrast medium, valsalva maneuver will often balloon out the paretic side in the case of neurologic tenth nerve deficit. It may also better outline the borders of a pharyngeal tumor if this instead should be the cause of dysphagia.

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The Waterbury Influenza Epidemic of 1918/1919

Gert Wallach, M.D., M.P.H.

Where can the citizen, faced with a potential disastrous epidemic, obtain information on what to expect? Where is the body of knowledge which can transform the horror of the vague and half-known into reasonable certainty that can be confronted and overcome by action? Obviously the answer is in the study of the terrible "Spanish" influenza disaster of 1918/1919 that might have its repeat this winter.

There are many ways this horror can be researched. There are the reminiscences of the oldtimers; there are newspaper files and there are the records of the Health Department. All of these can make valuable contributions. In addition, there are the death certificates. They cannot tell us how many citizens became ill but they are complete as to the numbers who died. There might be some inaccuracies in diagnosis but comparatively they are the most reliable source. This paper will limit itself to them.

The epidemic started in September 1918 gradually. The local Health Department received its first report of influenza on the 25th and on the 30th the first death by this illness was certified.

In Connecticut as a whole, however, the illness had begun earlier and with a big bang. Since the first of the month, 8,070 cases and 3,061 deaths were reported to the State Department of Health. By hindsight, however, it can be said that the illness began in Waterbury earlier than indicated above. In September, the death rate from pneumonia was twice as great as in 1916 and 1917, and 58% of the victims were between age 13 and 39 as compared to about 12% in previous years. There was also one death with the unusual diagnosis of "Pregnancy Pneumonia."

Waterbury was therefore unprepared for the horrifying wrath of October when the city was worse hit than any other place in the state. Seven hundred and fifty-three persons died from influenza during that month, not including those succumbing elsewhere and the boys in the armed forces. In the space of thirteen days, five members perished in one family and at least in one other, four. Nineteen mothers succumbed during pregnancy. Most frightful was the age distribution of the victims as two-thirds of the dead were in the most productive life span between 20 and 39 years and three out of four between 13 and 49. The elderly and the chronically ill were not much affected. Only one out of 120 of the dead were 60 years and older. The

infants and children were worse off. One hundred and twenty-seven under the age of seven, or one of about six of all deaths, were in this group.

After October the epidemic subsided. Deaths continued all through the spring and summer of 1919, but after March the number became so small that this survey is ended with March 31.

Table 1
REPORTED DEATHS FROM INFLUENZA CONNECTED ILLNESSES
AND OTHER CAUSES IN WATERBURY, CONNECTICUT
SEPTEMBER 1918 THROUGH MARCH 1919

	<i>Influenza Connected Causes</i>		<i>Non-Influenza Causes</i>		<i>Total For Month</i>
September 1918	12	(11.1%)	96	(88.9%)	108
October 1918	753	(89.5%)	88	(10.5%)	841
November 1918	86	(54.1%)	73	(45.9%)	159
December 1918	67	(40.9%)	97	(59.1%)	164
January 1919	71	(41.5%)	100	(58.5%)	171
February 1919	49	(36.8%)	84	(63.2%)	133
March 1919	33	(26.3%)	93	(73.8%)	126
Total	1,071	(63%)	631	(37%)	1,702

The sex distribution of the victims showed excess of the male population (54.5%) but this is not significantly different from the usual male preponderance. It is note-worthy that the greater male rate was largely due to the greater rate during the peak of October. During three of the other months more females succumbed.

Table 2
INFLUENZA DEATHS SEPTEMBER 1, 1918 TO MARCH 31, 1919
SEX DISTRIBUTION

	<i>Male</i>		<i>Female</i>		<i>Total For Month</i>
September 1918	4	(33.3%)	8	(66.6%)	12
October 1918	415	(55.1%)	338	(44.9%)	753
November 1918	58	(87.4%)	28	(32.6%)	86
December 1918	28	(41.8%)	39	(58.2%)	67
January 1919	37	(52.1%)	34	(47.9%)	71
February 1919	27	(55.1%)	22	(44.9%)	49
March 1919	15	(45.5%)	18	(54.5%)	33
TOTAL	584	(54.5%)	487	(45.5%)	1,071

The age distribution of the victims never changed significantly from the pattern established during October 1918 through the overall death rate or persons over sixty finally reached 2.3%.

DR. GERT WALLACH, Director of Health and Registrar of Vital Statistics, Waterbury, CT.
EDITOR'S NOTE: This article was received June 1976.

Table 3
INFLUENZA DEATHS IN WATERBURY, CONN. SEPTEMBER 1918 THROUGH MARCH 1919.
AGE DISTRIBUTION

	MONTHS						YEARS							Total Each Month
	Less than 1	1 through 11	1 through 3	4 through 6	7 through 10	11 through 12	13 through 19	20 through 29	30 through 39	40 through 49	50 through 59	60 and over		
September 1918														
Deaths	—	1	1	—	1	1	1	4	2	—	1	—	12	
Percentage		8.3	8.3		8.3	8.3	8.3	33.3	16.7		8.3			
October 1918														
Deaths	11	29	68	19	16	13	47	250	213	65	16	6	753	
Percentage	1.5	3.9	19.0	2.5	2.1	1.7	6.2	33.2	28.3	8.6	2.1	0.8		
November 1918														
Deaths	3	9	9	1	2	—	3	20	26	8	5	—	86	
Percentage	3.5	10.5	10.5	1.2	2.3		3.5	23.3	30.2	9.3	5.8			
December 1918														
Deaths	2	1	4	1	—	—	9	17	15	5	5	8	67	
Percentage	3.0	1.5	6.0	1.5			13.4	25.4	22.4	7.5	7.5	11.9		
January 1919														
Deaths	1	7	4	2	2	—	4	14	19	7	6	5	71	
Percentage	1.4	9.9	5.6	2.8	2.8		5.6	19.7	26.8	9.9	8.5	7.0		
February 1919														
Deaths	4	4	4	2	—	—	1	12	9	7	1	5	49	
Percentage	8.2	8.2	8.2	4.0			2.0	24.5	18.4	14.3	2.0	10.2		
March 1919														
Deaths	1	8	5	1	—	—	1	1	9	2	4	1	33	
Percentage	3.0	24.2	15.2	3.0			3.0	3.0	27.3	6.0	12.1	3.0		
Total Deaths	22	59	95	26	21	14	66	318	293	94	38	25	1,071	
Percentage	2.1	5.5	8.9	2.4	2.0	1.3	6.2	29.7	27.4	8.8	3.5	2.3		

The death certificates of the time required that a primary and a secondary cause of death be filled in by the treating physician as of today. The doctors fulfilled this duty painstakingly, as a matter of fact so meticulously, that one wonders how they could find the time during an epidemic. Many gave more information than was requested, and in the great majority there is no difficulty to assign the deceased to a particular cause of death. Difficulties arose when there were diagnoses, as influenza pneumonia, meningitis, or pneumonia pregnancy. Modern concepts and usages rendered additional problems, and the lack of an accepted standard as to primary and secondary causes, another. Clearly, some regularity had to be established to arrive at meaningful statistics.

The following principles were adhered to in this paper:

- A) Influenza was considered the secondary cause of death unless no complications were indicated.
- B) During the months considered, all pneumonia, bronchial pneumonia, bronchitis, etc., cases were always considered as influenza complications according to modern usage.

- C) Pneumonia meningitis was listed under meningitis.
- D) Pneumonia pregnancy was listed under pregnancy assuming that the pneumonia might not have developed if pregnancy had not been present.
- E) Chronic diseases were considered the essential factor, assuming again that death would not have occurred without them.
- F) Prematurity due to influenza of the mother was assumed to be a primary cause.
- G) Acute complications were listed as primary if they were connected with "Influenza" alone, otherwise they were disregarded.

These data should give additional arguments to those who stress the preventive inoculations in preference to treatment of pneumonia or its prevention by prophylactic prescriptions of antibiotics. Many victims did not die from pneumonia.

There is also some doubt whether chronic illnesses should receive such high priorities though they are certainly of importance.

The pregnant woman should receive more attention. Inoculation should be received before pregnancy

Table 4
CAUSES OF DEATH DURING THE INFLUENZA EPIDEMIC IN WATERBURY,
CONN. SEPTEMBER 1918 THROUGH MARCH 1919

	INFLUENZA	PNEUMONIA, ETC.	PREGNANCY	PREMATURITY	MENINGITIS	CHRONIC DISEASES	ACUTE COMPLICATIONS
September 1918	—	11 91.7%	1 8.3%	—	—	—	—
October 1918	94 12.5%	618 82.1%	19 2.5%	5 0.7%	3 0.4%	10 1.3%	4 0.5%
November 1918	7 8.1%	71 82.6%	—	1 1.2%	2 2.3%	1 1.2%	4 4.7%
December 1918	3 4.5%	49 73.1%	2 3.0%	1 1.5%	3 4.5%	5 7.5%	4 6.0%
January 1919	2 2.8%	54 76.1%	3 4.2%	1 1.4%	2 2.8%	4 5.6%	5 7.0%
February 1919	—	38 77.6%	3 6.1%	—	3 6.1%	5 10.2%	—
March 1919	—	27 81.8%	—	—	4 12.1%	2 6.1%	—
TOTAL	106 9.9%	868 81.0%	28 2.6%	8 0.7%	17 1.6%	27 2.5%	17 1.6%

begins, otherwise pregnancy should be prevented if possible.

Conclusions
Connecticut's experience with the influenza epidemic of 1918/1919 appears to have been about the same as Waterbury's. This has wide-ranging implications for the management of the potential epidemic of this fall and winter.

- 1) The Waterbury epidemic (and Connecticut's) started in September, not in December when influenza usually begins. This early start is not an isolated irregularity. The peak month of the Asian influenza of 1957 was in October also. The inoculation program must be expedited as quickly as possibly.
- 2) The priority list must be altered completely. Individuals between the age of 13 and 49 constitute about three out of four of the victims and are the high risk group, not the elderly and the chronically ill. The 13 through 49 year olds should be inoculated first and the potential early start of the epidemic makes this even more urgent. The elderly and chronically ill should wait until other groups are taken care of. The immunization of the new high risk group should start immediately.
- It might be desirable to immunize whole families together in certain settings. This should be encouraged if it does not delay the rapid program with the primary high risk group.
- 3) Waterbury's data of 1918/1919 indicate that children should *not* be considered to be generally immune against the serious consequences of the potential onslaught. In 1918/19 about twenty-two percent of the fatal victims were children below the age of thirteen; about three of four of these were three years and younger. Children should be protected as soon as suitable material becomes available.
- 4) Unless the expectant mother is inoculated, pregnancy should be discouraged until the danger of the epidemic has passed.

REFERENCES
The 1702 death certificates of the Vital Statistics Section of the Waterbury Department of Public Health and Records of the Connecticut State Department of Health.

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PHYSICIAN OR LABORATORY **DR. G. SMITH** ACCOUNT NO. **1042B** ID NO. **000343**

SAMPLE DATE **3/9** DATE RECEIVED **3/9** REMARKS **FASTING** LAB NO. **1**

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USUAL NORMAL RANGES

10	26
0.7	1.4
6.0	8.5
30	55
150	270
140	175
30	80
2.5	110
2.5	4.5
37	184
2.4 gms/dl	
10-1	

BUN	10.26 mg/dl	18	mg/dl
Creatinine	0.7-1.4 mg/dl	3.6	mg/dl
Total Protein	6.0-8.5 gm/dl	6.4	gm/dl
Albumin	3.0-5.5 gm/dl	3.3	gm/dl
Cholesterol	>40 150-330 mg/dl <40 140-270 mg/dl	154	mg/dl
Triglycerides	30-175 mg/dl	107	mg/dl
Uric Acid	2.5-8.0 mg/dl	3.4	mg/dl
Calcium	9.0-11.0 mg/dl	8.1	mg/dl
Phosphorus	2.5-4.5 mg/dl	3.8	mg/dl
Serum Iron	37-184 mcg/dl	223	mcg/dl
Globulin	2.4 gm/dl	3.10	gm/dl
BUN/Creatinine	10:1 Ratio	31	25

FASTING

827

SEQUENCE NO.

Total Bil

SGOT

SGPT

Alk Phos

LDH

Sodium

Potassium

Chloride

Carbon Dioxide

A/G Ratio

SGOT/SGPT Ratio

1.1 mg/dl

16 U/L

48 U/L

123 U/L

177 U/L

131 meq/L

4.0 meq/L

98 meq/L

25 meq/L

1.06

0.33

USUAL NORMAL RANGES

0.2	1.2
0	28
0	45
30	115
100	235
120	135
145	
35	50
96	106
19	26
1.1-1.8	

TEST	NORMAL RANGE	RESULTS
GLUCOSE	65-110 mg/dl	100
P.B.I.	4.8 mcg/dl	
T.T.	4.10 mcg/dl	
T.3	35-45 %	
T.4	4.5-11.5 mcg/dl	
T.7	1.5-5.2	

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Factitious Contributions to a Staphylococcus Sepsis

Mahlon S. Hale, M.D.

Case Presentation

The patient is an 18-year-old, single white female, born in Canada, who appeared in the emergency room of this hospital with complaints of nausea, vomiting, severe abdominal pain, stiff neck, myalgias, headache, chills and fever. These problems apparently began one week prior to admission but had not prompted the patient to seek medical attention until their worsening and a final dramatic presentation. She denied any accompanying cough, hematemesis, upper respiratory tract infection or recent urinary tract infection. There was no history of any contact with ill individuals or any recent travel other than a temporary move to suburban Philadelphia two months earlier for employment. At that time other serious medical problems occurred. According to the patient, she accidentally cut her left forearm on a test tube while working as a technician in a medical clinical laboratory. Seven days later, she was admitted to a local hospital with a *Staphylococcus aureus* infection. She received one week of intravenous Oxacillin treatment and was discharged on 500 mgs. of oral Keflex q6 hours. Ten days following her discharge, she was re-admitted for HAA-positive hepatitis. This hospitalization lasted for ten days. A third, short admission followed for continued nausea, vomiting and dehydration. The patient received supportive therapy for one week and was discharged. She reported no medical sequelae until the week prior to her admission at this hospital.

Once on the inpatient medical unit, the patient presented as an intelligent and verbal young woman, able to tell her story in considerable detail. Physical examination revealed a small, obese female who appeared septic and in moderate distress. Her blood pressure was 110/46 and her pulse 100. She had rapid and shallow respirations and a temperature of 102°. Bilateral small tender anterior cervical nodes were noted. Fundi were clear and the sclerae were also clear and nonicteric. The skin was without petechiae, Janeway spots or Osler nodes, and there were no splinter hemorrhages. The chest was clear to percussion and auscultation. The PMI was in the 5th intercostal space at the mid-clavicular line. No murmurs or gallops were heard. Peripheral pulses were equal and intact. The abdomen was diffusely tender with general guarding, but there was no rebound, and bowel sounds while decreased were present. There were no palpable masses or organomegaly. The patient's extremities showed bilateral small axillary adenopathy not tender to palpation. There were positive Kernig and Brudzinski signs. With these exceptions, the neurological examination was intact. Laboratory data showed a white count of 1600/mm³ with 57% polys, 42% lymphocytes, and 1 monocyte. The hemoglobin was 13.5 g/dl and the hematocrit 38.8. There were 178,000 platelets/mm³ and clotting studies were unremarkable. Electrolytes were within normal limits. Urinalysis was negative. The chest X-ray, electrocardiogram, and lumbar puncture were within normal limits.

The patient's hospital course proved to be lengthy, complicated and perplexing for the ward staff. On the first hospital day, 12

culture bottles were drawn, 6 of which grew out *Staphylococcus aureus*. The patient was placed on intravenous Oxacillin and did well for the next four days with rapid remission of her signs and symptoms. On the fifth day, however, the initial complaints reappeared and were presented to the staff word-for-word as they had been presented in the emergency room. The patient remained afebrile but on re-examination a murmur was heard and there was a question of a re-exacerbation of the staphylococcal sepsis. The concern at this point was that the patient had endocarditis or was seeding from another focus. During the next two weeks she underwent an echocardiogram, a bone scan, brain scan, IVP, chest films, two liver-spleen scans, a Gallium scan, an abdominal echo, a second IVP, a second ultra-sounding of the upper abdomen and numerous serological tests, all of which were reported as normal. Further concern for abdominal pathology stemmed from the fact that the patient's abdominal pain with which she had presented had become progressively worse and localized in the upper left quadrant. In addition she developed a large ecchymotic area with a centralized excoriated lesion over this area. She also complained of severe left CVA tenderness. Complications considered at this time included perinephric abscesses as well as splenic infarctions, but these could not be documented. All subsequent blood cultures remained negative. Heavy metal screening was also negative. A collagen vascular workup was negative. Consultations obtained from the infectious disease and surgical services did not clarify the situation. During this period, new complaints of diffuse pain emerged for which she received meperidine and morphine. During the last week of hospitalization the staff noted elevations in the patient's fever not duplicated when a member of the nursing staff remained in attendance. Further, the patient acted bizarrely to the insertion of a subclavian line with arching of her back, hyperventilation and screaming. She complained specifically of a pneumothorax secondary to the insertion of the line but no pneumothorax could be found on chest film. Following the insertion of this line the stop valve was opened and the line found clotted. At this point psychiatric consultation was requested. The patient was very negativistic towards this consult but, with the appearance of the psychiatrist, stated that some of her history, though not the history preceding hospitalization, was confabulatory. As the patient's psycho-social history was elicited, it became apparent that psychiatric intervention would be appropriate. When inpatient treatment was suggested, the patient consented but then signed out of the hospital against medical advice. It is of interest that after the psychiatrist placed the patient on low dose perphenazine, she had an oculogyric crisis that was treated by a house-officer with a saline injection. At the time the patient left the hospital she had received 21 days of intravenous Oxacillin therapy. She did not return for follow up. Following the consultation, the patient's family found a note written by the patient prior to her hospitalization that described her role in precipitating her illness and then elaborated in fantasy possible outcomes, including a downhill course and a sudden reversal leading to a miraculous recovery.

Discussion of the Case

The case for discussion presents a distinctly differ-

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ent set of problems from those usually seen on medical services. A patient who for unclear reasons deliberately contributes to his illness in terms of onset, prolongation and eventual outcome throws medical services into quandaries, not only around modes of treatment, for treatment is soon derailed, but also around the questions "What are we treating?" and "Whom are we treating?". Without a doubt the patient presented here had a staphylococcal septicemia. Complicating her management were chameleon-like qualities to her multiple and varying symptoms, the perception by staff of the factitious nature of new complications, the subsequent question of self-inflicted disease, the patient's eventual conflictual status with the staff, consequent disruption of management, and lastly, her loss of credibility when a component of her illness came to be seen as psychiatric rather than medical. It is one thing to treat a sepsis for six weeks and to be on one's guard to secondary foci, endocarditis and other complications, and quite another to find oneself treating a patient whose role in the evolution, maintenance and possible elaboration of her illness is brought into question. When behavior that deviates far from the norm of what we expect from other patients colors all treatment plans, we become very uncertain. When staff suspicions of patient contributions are confirmed, surprise and anger are the result. How this reaction fits into the design of the patient is still speculative. But the evocation of such emotions on the staff infinitely complicates treatment and leaves the patient in control.

In practical terms, this young woman presented with factitious elements in a very serious illness. Her note, whether a piece of bonafide history or the work of fantasy, achieves significance as confirmation of her design. It had a final negative effect upon medical management and the staff's attitude toward treating such a patient. Psychiatry does not fare much better. It is safe to say with such a case that when the psychiatrist enters the field of battle, he finds two warring factions. The patient is furious at being undone and the staff is unable to cope with the idea that its work has been the response to a partial fabrication, or to use the words of William Bean, "a nearly perfect facsimile of serious illness".¹ These fabrications when they are pure or enhanced by the sequelae of earlier medical and surgical interventions are known as the Munchhausen syndrome, that eponymous disease named after the Baron von Munchhausen and Raspe's fictionalized account of his adventures.² This case is somewhat different in that the patient, willfully or not, presented with a major life-threatening illness intertwined with the usual misleading physical signs and distortion of history that we attribute to this un-

common, chronic factitious illness. Nonetheless, a carefully taken psycho-social history of this patient revealed elements typically associated with cases of the Munchhausen syndrome, and I would speculate that we have witnessed an early chapter in the adventures of this patient. One common element in the histories of such patients is childhood exposure to a major illness.³ In this case, our patient at the age of six was hospitalized for nine months in a sanatorium for tuberculosis which she had contacted from her mother who was simultaneously hospitalized. Second, those few Munchhausen patients seen for any period by psychiatrists have reported being raised in homes characterized by family divisions and parental illnesses.⁴ Again, this patient reported growing up in a home where alcoholism caused frequent parental separations, and where the patient's mother had undergone periodic tumor surgery over the preceding 15 years. Lastly, like the colorful baron himself, the patient initially presented with a hyperbolic history frightening in its impact for those responsible for her care. A confirmatory clue as to the confabulatory quality of this patient lay in her reports of dramatic vignettes of a tragic personal history including the death of a boyfriend during the previous year from a mysterious neurological illness. This in fact could not be confirmed from any record by the psychiatrist who volunteered to track down the nature of this illness and the patient subsequently admitted the fabrication. What is missing from the chronic course is the history of hospital vagrancy characteristic of the Munchhausen syndrome. However, on further inquiry the psychiatrist learned there had been numerous contacts with physicians during the patient's teenage years felt by her parents to be for symptoms of minor importance and that in the year prior to this hospitalization, as reported by the patient, involved an upper respiratory tract infection accompanied by fever. She volunteered the information that emergency room physicians were unwilling to admit her until at her request they did a white cell count and found a substantial leukocytosis. Both the fever and the elevated white count remitted without any conclusive diagnosis being made. Following this hospitalization the patient had another hospitalization reminiscent of the pattern prior to this admission in which she presented with hyperventilation. So there are more than intimations of such travels. Indeed, as of this writing, the patient has been admitted to The Stanford University Hospital in Palo Alto, California with an identical presentation.

It is of interest that the literature on this syndrome gives much descriptive information on the characteristics of these patients but has little to recommend so far as treatment and a reduction of the chronic course are concerned. Richard Asher in a 1951 *Lancet* article

coined the term Munchhausen's syndrome in describing three groups of patients who like the Baron von Munchhausen, at least in his fictionalized presentation, traveled widely, had extraordinary adventures, utilized dramatic recitations and held the truth in low esteem.⁵ Asher's initial categories were abdominal types, the hemorrhagic types and the neurological types, but subsequently wider and rarer presentations have been reported including factitious cardiac disease, renal colic and pulmonary edema.⁶ Fevers are of course the target of factitious presentations and in the classic Petersdorf and Beeson article on F.U.O., two cases in the original 100 were eventually attributed to factitious illness.⁷

Of more help to us would be some knowledge as to the motivation for such behavior. At this time our knowledge of the underlying psychology is still hypothetical but some observations can be made. First, it cannot be simply fortuitous that these persons select the medical arena for their dramatic presentations. Second, a striking feature they all possess is that of impostorship with the ability to know and control the prospective course of their illness. Some authors have tried to explain the disorder on the basis of the sociopathic and hysterical traits found in their personalities.⁸ This is merely another way of saying that such patients manipulate us and do so in an extravagant and histrionic manner and out of what appears to be their own volition, though one cannot help thinking that there are strong unconscious factors as well. One further aspect of their drama is that they are inevitably the final victims of their falsifications. If they seek

a medical arena to act out what is known as the "doctor game", their impostorship is such that they are inevitably rejected and suffer the more. One does not need a psychiatrist to point out the overwhelming masochism in such a process. If the patient seeks in the physician a substitute parent, he inevitably promotes his own rejection by disruptive behavior and a history that is viewed as deceitful. One would like to think that premonition would allow us physicians to intervene and defuse such presentations before the usual outcome. But the patient's own need to control the situation inevitably leads both physician and patient to the crossroads where treatment for the underlying illness cannot be given because so much damage has been done to the relationship and so much credibility of the patient lost.

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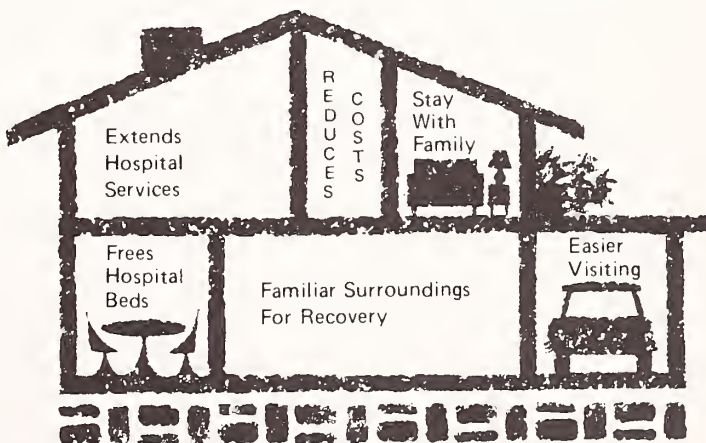
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Humanistic Issues at the Interface of Nursing and the Community

Sally A. Gadow, R.N., Ph.D.

A program which attempts to address humanistic issues in nursing requires an initial identification and even systematization of those issues. Haphazard selection of problems and topics on the basis of current movements, popular themes, or recent judicial decisions will inevitably ignore some issues and overemphasize others.

At least two possibilities for more methodic delineation of issues are available, if we think of the humanities and nursing as the two disciplines that the proposed program seeks to unite. One method is to identify and organize issues from the side of the humanities, i.e., according to the three distinct approaches to human experience that the humanities represent: the historical, the aesthetic, and the philosophical. The second possibility is to delineate issues from the side of nursing, and then determine which of the several humanities approaches offer the clearest elucidation.

Since current humanities teaching in health professional education tends to use the first method, i.e., to address those issues which fall within the purview of the particular humanities disciplines that happen to be represented by the faculty, I will briefly consider that method first. (My bias will be evident, for I will devote the greater portion of my discussion to the second method, which seems the more promising for our purposes.)

In looking at nursing from the three humanities perspectives which I distinguished—the historical, the aesthetic, and the philosophical—we can identify different areas of concern. The historical approach fo-

cuses upon questions about the origin and evolution of present values and coming changes in nursing. Thus the use of historical studies would be especially relevant in addressing issues, for example, around the involvement of nurses in modifying traditional health care systems. The aesthetic approach, with its focus upon the unique, non-quantifiable dimensions of human experience, would appropriately address such issues as the subjective and expressly individual aspects of the experience of illness, as portrayed, for example, in literature. Finally, the philosophical approach, often the only one employed in humanities teaching in health care settings, obviously addresses issues of the moral permissibility of certain practices, as well as the more difficult issues of, not right and wrong, but permissible versus ideal ways of caring for persons. Beyond these ethical issues, philosophy is also concerned with questions about the nature of humanness and the fundamental forms of human relating; thus it would address, for example, the issue of which particular form of relation constitutes the basis for the nurse-patient relation.

I turn now to the second method, that of delineating issues from the side of nursing rather than via the humanities approaches. It is this method which I propose as the more useful tool for us in identifying the so-called humanistic issues, and I do so with the following rationale. There is no division in nursing (or in any human services profession) between humanistic and non-humanistic issues. The principal elements of the nursing process are persons, and thus the human, the unique, non-technical value dimensions are by definition an essential aspect of the practice of nursing. There is, in other words, no element of nursing which is without humanistic issues. In seeking to identify those issues then, a natural method seems to be for us to lift out *all* of the fundamental issues in nursing on the assumption that all of them are in principle humanistic. The next step would be to explore the ways in which each of those issues can be most appropriately addressed and elucidated by one or more of the three humanities approaches.

Since I have asserted that the important components of the practice of nursing are the human beings involved, a natural organization of issues suggests itself, based upon the various interrelations of those

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persons. The issues would thus cluster in this way, emerging around these relations:

a) *The Nurse and the Patient* (I use the term "patient" simply from custom, rather than as a resolution in advance of the important issues reflected in the range of terms now in use, from "patient" to "client" and "consumer".)

b) *The Nurse and Other Health Professionals.*

c) *Nurses and Nursing.*

d) *The Nurse and the Community.*

I would now like to propose formulations of some of the specific issues within each of these categories, and formulations of particular humanities approaches that might address those issues.

I. The Nurse and the Patient

A. Defining the Nurse-Patient Relation: What are the historical and the present forms of the nurse-patient relation, and what may the ideal relation be to which both nurses and the public would agree and aspire? The possibilities are not unfamiliar to anyone who has provided or received nursing care: the nurse as parent-surrogate, healer, physician surrogate, contracted clinician, patient advocate, health educator, or provider of some unique and yet undefined type of care falling within none of the stereotypical nurse-patient relations, or, finally, (as my students always insist) a grand and unique synthesis of all of the above.

One approach to this issue is a phenomenological inquiry into the experience of illness, to elucidate the distinction between the body as an external object and the body as a lived interiority. The implications of that distinction for nursing are becoming apparent. To cite one example: studies by nurse researcher, Dr. Jean Johnson, have shown that post-operative patients were affected more positively (in terms of less analgesia, shorter hospital stay, etc.) when given preoperative information about the subjective sensations they might experience after surgery than when given a description of the objective phenomenon they would undergo, viz. the surgical procedure. The question of whether nursing should ideally address the individual as a lived subjective body, or an organ-system object-body, or a unity of the two, is surely one that has implications for the nature of the nurse-patient relation.

A second philosophical concern with the body and illness is the issue of the value of suffering, or the religion of health. Existentialists maintain that we are free to determine the meaning that any experience will have for us, no matter how anguished or unfree we feel. Nietzsche makes a still stronger claim that pain is a positive, even necessary, means of finding one's own way, of creating oneself, and the sympathy of those

who rush to comfort us only devalues our experience. The question then of whether suffering is a defect of human existence or a uniquely human possibility for self-determination is one which nursing must address. If suffering is an experience the meaning of which—to be a truly human meaning—must be decided by each individual (unencumbered by the health professions' negative value of illness), then the task of the nurse becomes infinitely complex, in assisting each patient in an individual manner to establish the particular meaning that his or her suffering is to have.

In addition to the approaches of phenomenology and existential philosophy, the perspective of history is essential in helping clarify the extent to which the traditional role of the nurse as steadfastly caring and minimally technical has been a function of the level of technology involved in health care. Without question, the role of the modern nurse encompasses far more knowledge and skill concerning equipment and apparatus than has ever before been the case. Does the advancement of technology in nursing signify a necessary concomitant: a decline in the customary caring which has characterized nursing? Is nursing faced with a decision between preserving its commitment to *caring*, on the one hand, and following the progress of medical science with more technically intricate *curing*?

B. Ethical Problems Unique to the Nurse-Patient Relation: Are there any?

What are the moral implications of the particular type of relation that exists between nurse and patient? Are there ethical decisions which nurses should be prohibited from making, just as there are clinical/therapeutic decisions they are not permitted to make? Or, on the contrary, do nurses have ethical responsibilities to patients that even surpass those of other professionals less intimately and continuously involved with the patient? A philosophical analysis of such ethical issues would have to address the fundamental nature of the relation between a person who needs care and one who assumes responsibility for rendering that care. For example, does the patient have the right to receive from the nurse information withheld by other professionals? Does the nurse, if acting as parent surrogate, have the right to act paternalistically when the patient does not make "healthy" decisions? Does the nurse, if acting in contractual partnership with the patient, have the right to withdraw care when the patient refuses to assume responsibility for his or her health? Does the nurse, if acting as healer, analogous to the physician, have the right to cultivate the placebo effect that is thought to accompany all of the actions of a healer, even to the point of patent deception? Or does the nurse, if acting as patient advocate, have an obligation to protect the patient from

every erosion of human dignity and value, including deceptions in the name of health? Finally, if nursing is a synthesis of all of these roles, how are values reconciled when the roles conflict, as they often clearly do?

II. The Nurse and Other Health Professionals

The relation between nurses and their colleagues in health care has become a pressing issue because of at least two developments: the emergence of new health professions with which the traditional professions must articulate, and the increasing autonomy of mid-level practitioners as physicians become willing to delegate more of their tasks and authority. The issues for nursing can be formulated in the following ways: (1) What does the increasing number of independent nurse practitioners signify for the future of nursing? Is nursing practice striving to become another version of medical practice rather than an alternative and complementary form of care? Or are nurse practitioners seeking to offer a true alternative to the traditional medical practitioner by providing the same general care but in a different fashion? If so, what is that difference? And why is an alternative thought to be necessary? (2) A second issue is the changing relation between nurse and physician in their roles as members of the health care team (as distinct from their roles as independent practitioners). Nurses are becoming increasingly responsible and critical concerning the quality of care patients receive from their physicians. Nurses challenge orders to resuscitate, orders not to resuscitate, and at times simply make decisions directly contrary to orders which they think unjustified. The nurse is of course professionally obligated to challenge a medically unsafe or unsound order. Is there a comparable obligation to refuse an order that is ethically indefensible in the nurse's view? Does the physician's ethical as well as medical opinion have more authority than that of the nurse (especially when the latter is in agreement with the expressed view of the patient)? Should the nurse, in other words, be legally required to honor an order, such as the directive to continue intravenous fluids for a terminal patient—or to discontinue them—when the order is based solely on the physician's moral view of the case in question and rests entirely on values, as many decisions in health care inevitably do?

Here, the disciplines of history, law and moral philosophy are all needed in addressing such an involved issue as the legal, ethical, and professional divisions—past, present, and future—between nurses and other health care providers. One approach that might prove interesting as well as bring issues quickly to the surface would be an interprofessional debate of a hypothetical clause in California's "right to die" legislation allowing the nurse to assent to a patient's request for

discontinuing extraordinary life-sustaining measures when the attending physician refuses to do so.

III. Nurses and Nursing: The Relation of Nurses to Themselves and Their Profession

A. *Images of Women Healers in Art and Literature.*

Because 97% of nurses are women, and because many of the issues around the nurse-patient and the nurse-physician relation are entangled with issues of women's history, as evidenced by the cliché of the nurse as mother of the patient and wife of the physician, it would seem crucial to address explicitly and directly the relation between women and nursing. One way of clarifying that relation is by examining images of women and women healers in literature and the visual arts. Such an inquiry would constitute an historical as well as aesthetic approach by documenting the images of women that cultures have expressed through their artists, images that not only are reflected in art and literature, but may in part be created by artists and writers.

B. *Women in the History of Health Care*

Another way of clarifying the relation between women and nursing is to examine historically the situation of women in the health sector, which would entail analyzing not women as such, but the socioeconomic and political systems that generate and perpetuate the present situation of women. If the traditional role division within the family is accepted as part of the basis for the sex hierarchy in the health sector, critical historical studies of the family are required for elucidating the (so to speak) family structure of the health team, with its male leader, female auxiliary, and devoted dependents. On the other hand, since the study of history offers us interpretations rather than facts, it would be simplistic to conclude that the same social and economic needs that seem to have delegated the role of nurturing support to women in the family are also the reason that nursing has been traditionally a role of "motherly care." If that were the case, we would have to predict that the liberation of women will mean the liberation of nursing, but it is not clear that the caring functions of the nurse are entirely analogous to those of the mother, or that—even if they are—nurses would want to discard them for more "liberated" functions.

C. *Holistic Nursing: Whole Nurse or Whole Patient?*

It is often maintained that optimal healing depends upon the interaction of both patient and professional as whole human beings. This is then translated into concern for the patient as a unique psychobiological whole that is self-responsible and self-healing. What is lost in that translation is the professional. To what extent is the whole person of the healer—in this case

the nurse—a necessary corollary for optimal healing of the whole patient? In recent years, nurses have been acutely concerned with achieving full professional stature as health care providers. Is the commitment to professionalism antithetical to the concern for holistic, or whole-person, healing of the patient if that in any way requires whole-person involvement of the nurse? The distinction between personal and professional involvement has been kept carefully sharp, ostensibly for the protection of the patient. Patients now complain that their care is too impersonal. Do they mean too professional? Or are they simply responding to the movement of humanistic health care, which I interpret as the movement to soften the distinction between personal and professional, as the practitioner becomes more fully, subjectively as well as objectively, involved, more human, while the patient becomes more knowledgeable, assuming responsibilities for health and decision-making formerly the sacred domain of the professional?

This issue, I propose, is not best addressed by the humanistic psychologies, although they can surely be credited with much of the personalization of the professional. The issue requires a sound and new conceptual framework within which to develop means for unifying and transcending the once contradictory relation between professional and personal. What seems to be needed is, among other things, a more ample and complex, and thus more human, concept of the body. Efforts at rehumanizing health care cannot survive confinement to a concept of body that belonged to medicine when it was hoped to be an exact science and the practitioner a scientist—or, in the case of the nurse, a research assistant—whose objectivity was inviolate, if at times untherapeutic. The task of addressing the problem belongs to philosophy and art, philosophy providing a conceptual re-examination and a phenomenological rediscovery of the whole person as body, and the arts providing aesthetic, non-analytic access to human experience through images of the body that the artist portrays. A single work with the impact of Degas' tender painting of a girl-woman sitting unclothed on a bed, bewildered, wondering, can in itself make the point that one's experience and image of one's body are so intimate and inward, and often excruciatingly fragile, that the height of dehumanization would be an objective, "professional" treatment of the body as an external object, a clinical entity.

IV. The Nurse and the Community

A. Community Control: Nursing and a National Health Service

The insulation of the health industry from the needs of the community is slowly diminishing. Consumer-

ism, plus the public consciousness-raising with respect to health and health care, mean that all of the health professions will be held increasingly accountable for the distribution of practitioners, both in geography and in specialty, and for their professional training, particularly as it concerns the values of human dignity, quality care, and nondiscrimination. The issue for nursing is thus the extent to which the profession can and should share with the public the responsibility for adjusting the maldistribution of health workers. A related issue is whether that adjustment should extend to the very foundation of health care, viz. professional education, with the possible effect that the levels within the professional hierarchy would be equalized by educating health workers together in health team schools, with a basic curriculum for all categories of practitioners, and with control of admissions and curriculum exercised by community health boards. If this type of health service assured more equitable and rational distribution of care, what should the position of nursing be, particularly if public participation threatened to democratize health services to the point of eliminating distinctions between professions, or if the public were more interested in warm and personalized care such as nursing auxiliary persons sometimes supply than in the theoretical and technical mastery which the professional nurse possesses?

B. Nursing Values and Aging: Stereotype or Ideals?

In a nursing class last week on the subject of mid-life crisis, I heard students express almost unanimously a reluctance to contemplate middle-age because it is the prelude to aging, and aging seemed to them little better than dying. Their attitude, simply reflecting the prevalent social negativity toward aging, is not likely to change as a function of nursing education. Studies have shown that nursing students' stereotypic attitudes toward the aged are changed, if at all, by prolonged contact with elderly patients. The issue of how to change attitudes is, of course, the concern of educational psychology. The humanities must address the more fundamental issues: what images and ideals of the aged *should* health professionals be educated to have, in place of the negative stereotype of deterioration and decay? Are there more positive and freeing, and thus more human, meanings of aging that nursing and the humanities together can propose as alternatives to the concept of aging as a disease for which the cause and the cure have not yet been found?

The issue of more human meanings of aging is one for which nursing and the humanities are ideally suited to integrate their particular approaches to human experience. Historical studies are needed as basis for understanding alternative attitudes of other cultures toward aging, as well as the origins of present values—and disvalues—of aging in this society.

Against that background, an integration of the philosophical and aesthetic approaches can provide an interweaving of conceptual ideals and concrete images that express the positive meanings of aging as a human value. To this fabric of meanings that the humanities weave, the nurse brings experiential meanings of aging that evolve from sustained, intimate care of the aged, those human beings who as individuals defy generalization and succeed where ed-

ucational strategies fail in humanizing the stereotypic attitudes of young professionals. Presumably, education fails where the aging themselves succeed because the latter not only present but embody the human meanings of their experience, while education tries at best to neutralize negative values without offering vital, compelling alternatives. It is certain that together the humanities and nursing can articulate such alternatives.

DANAZOL IN TREATMENT OF HEREDITARY ANGIOEDEMA

National Institutes of Health scientists have shown that a new synthetic hormone, Danazol, prevents potentially life-threatening attacks of hereditary angioedema (HAE). In addition, the National Institute of Allergy and Infectious Diseases (NIAID) and the National Institute of Child Health and Human Development (NICHD) investigators have found that the drug acts to correct the inherited biochemical abnormality believed to cause the disease.

Hereditary angioedema is a rare but serious condition characterized by episodes of swelling of the hands, feet, face, or airway passages and recurrent abdominal pain. Although these attacks can occur without provocation anxiety, stress, or minor trauma, such as dental work, have been associated with an increased incidence of attacks. Deaths due to HAE, usually caused by airway obstruction, have been reported to be as high as 30 percent.

Lacking effective means of stopping an attack once it starts, patients with HAE have relied on long-term use of various drugs to prevent the attacks. However, these agents can produce serious side effects, thus limiting their usefulness. In addition, the prolonged use of one class of these drugs—androgens—by women with HAE can result in masculinization.

The NIH researchers, therefore, decided to study the effectiveness of a new androgen, Danazol, which has a reduced potential for producing masculinization. Five young women and four men who had a history of one or more HAE attacks each month received randomized courses of either Danazol or a placebo. Each course lasted 28 days, unless an attack occurred. A new course was begun either after successful completion of a 28 day course, or after an attack subsided. Neither the physicians nor the patients knew when a patient was taking Danazol or a placebo.

During 46 Danazol courses completed by the nine patients, only one HAE attack occurred. Side effects

of the drug were minimal: some weight gain in all patients, and menstrual irregularity in the women. However, the hormone did not produce virilization of the women nor affect the sexual potency of the men.

In sharp contrast, during the 47 courses of placebo in the same patients, 44 HAE attacks occurred.

In addition, the Bethesda researchers found that Danazol reversed the biochemical defect thought to be the cause of HAE—low amount and diminished activity of a protein which inhibits the first component of complement (a series of interacting serum proteins involved in immune responses). While on Danazol, the amount and activity of this inhibitor protein in these patients climbed to almost normal levels. One patient, who discontinued Danazol after 60 days experienced a decrease in the level of this protein until she resumed taking Danazol.

The scientists hope that any possible side effects of long term use of Danazol might be offset by lower dosages. Most of the patients, all of whom have chosen to remain on Danazol, have been able to decrease their daily dosages. No further toxicity has been seen even in those patients who have been on Danazol for six months.

Further study of Danazol's action in hereditary angioedema may provide a greater understanding of the underlying factors controlling and modifying this, and possibly other, genetic diseases.

The team of investigators, Drs. Jeffrey Gelfand, David Alling, and Michael Frank of NIAID and Dr. Richard Sherins of NICHD, reported their study in the December 23, 1976 issue of *The New England Journal of Medicine*.

This study was supported by NIH's Division of Research Resources H.E.W., Public Health Service, Bethesda, MD., January 1977.

Preceptorships and Medical Education

(First of Two Parts)

Stephen R. Smith, M.D.

The shortage of primary care physicians in rural and inner city areas is a growing national concern. The recently released report on primary care physicians in Connecticut by The Commission on Hospitals and Health Care indicated that 86 towns in the state have a shortage of primary care physicians.¹ Predominantly rural Eastern Connecticut towns have the highest physician shortage totals.

To address the problem of specialty and geographic maldistribution, attention has become focused on the concept of preceptorship training for medical students. This article outlines the history of preceptorship training and the role it has played and is now playing in undergraduate medical education. The second article will briefly describe the current activities in primary care preceptorship training in Connecticut.

Past History

In the pre-Revolutionary War period, approximately 90 percent of the practicing physicians in this country had received their medical education through preceptorship training. This system was copied from the apprenticeship system in England and Scotland. The first medical schools in the United States were established by the early 19th century, but their role was only to supplement preceptorial education with formal instruction, not replace it.

This relationship between study under individuals and study in institutions began to shift during the last decade of the 1800's. Steinwald and Steinwald² attribute this shift to two developments. Firstly, the scientific advancements being made in Europe emphasized scientific research as the basis of medical study. Secondly, the Flexner Report in 1910 criticized the lack of clinical training within most U.S. medical schools. These two factors which emphasized scientific investigation and clinical training led to the demise of preceptorships in medical education.

The shift in focus of medical education to the science of medicine led to a small backlash during the late 1920's. Preceptorship programs were introduced back into the curriculum at the Universities of Wisconsin, Michigan, and Vermont to counteract the extreme emphasis on science. The aim of the programs was to give students an opportunity to learn first-

hand about the art of medicine as it was applied in daily practice by the preceptors.

However, the Depression and war years dampened the interest in preceptorships. No new programs were instituted with the exception of the Duke University program in 1938 until the late 1940's.

A rekindling of interest in preceptorship training occurred in the 1950's. By 1955, there were about 25 schools with preceptorship programs. Nearly all these schools were state-owned schools. A major motivation of these programs was to encourage students to enter general practice and locate in rural areas. Nevertheless, the situation in rural areas became increasingly more critical and medical students were entering subspecialty training in increasing numbers. It was not until the late 1960's that the situation began to be turned around.

Recent History

The emerging interest in primary care that became evident during the late 1960's grew out of factors outside the formal medical science curriculum. In fact, the policies and practices in the academic institutions were the chief cause of increasing specialization. Admission criteria and selection processes selected students for specialization. This pathway was constantly reinforced by the curricula, educational processes, built-in reward mechanisms, relations between the academic community and the practicing community, and the post-graduate opportunities. At the same time career choice in primary care was discouraged.

In this atmosphere it is difficult to understand how any student interest in primary care emerged. The answer lies in part in the type of student entering medical schools in the mid-to-late 1960's. These students had been active in the civil rights movements and had developed a social consciousness. The exposure students received as participants in this racial and legal crisis sensitized them to the larger socioeconomic and political problems which hallmarked this period.

The threat of being drafted to serve in the Vietnam War prompted many of these students to apply to medical school. The students believed that medicine was a helping profession serving the people. However, once the students became more familiar with the actual state of affairs in medical science institutions, they recognized that, for the most part, the academic institutions were not at all being responsive to the real needs of the people. Health science institutions be-

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came no more immune to critical attack than did other established institutions which were seen as allowing social injustices to exist and people's needs to go unmet.

Students responded to this by affiliating with such activist groups as the Medical Committee for Human Rights (MCHR). This group has been established in 1964 to provide emergency aid to injured civil rights workers in the South.

Soon the students formed their own activist organizations. The first was created in 1965 by students from eighteen schools of medicine, dentistry, and nursing in the greater Los Angeles area. The purpose of the Student Medical Conference of Los Angeles was to provide "leadership through education, community service, and research."³

This group was to create the first nationally recognized interdisciplinary student health project. In the summer of 1965, thirteen SMC students (10 nursing, 2 medical, 1 dental student) worked in five locations in the San Joaquin Valley in California providing health services to the migrant worker population of the valley.

On April 23, 1965, the Medical Committee for Human Rights was formalized and consolidated at a meeting in Washington, D.C. Letters of invitation had been sent to fifteen Eastern medical schools and forty-five students from Howard, Tufts, Boston University, Harvard, Albert Einstein, and USC met in caucus and clarified the role of students in community activities.

This group formed the nucleus of a group that later met in the fall of 1965 at the University of Chicago Medical School and founded the Student Health Organization (SHO). This was a loosely organized interdisciplinary student group which sought to keep member schools informed of local group activities.

During the academic year 1965-66, the local groups began to organize efforts in community health including speaker forums, group discussions, and planning for summer activities. The University of Southern California acted as the sponsoring agency for the SMC in obtaining a \$204,000 demonstration grant from the Office of Economic Opportunity for a student project in Community Health Resources for the Poor.

The summer program provided fellowships for 90 medical, dental, and social work students from forty institutions in eleven states. The students worked in poverty areas in 9 counties throughout California coordinating their efforts with the agencies in the area. They provided actual service and learned first hand about the problems in delivery of health services.

At the conclusion of the project, the students were

generally enthusiastic and carried this enthusiasm back with them to their own schools. In 1967, SHO chapters had sprung up in thirty schools.

In the summer of 1967, the SHO conducted three major projects, one in New York, Chicago, and California. The projects placed 260 health science students from medicine, nursing, dentistry, social work, law, osteopathy, medical technology, medical sociology, and dental technology in these communities.

By April of 1968, the tide of student activism began to involve the largest, but heretofore inactive, health student group, the Student American Medical Association. Its House of Delegates and National Convention of 1968 had 800 medical students in attendance, representing 76 schools. Through resolutions adopted by its House and through its new dynamic leadership, SAMA became committed to action in community health.

In April of 1968, 10 SHO groups were carrying out local community health projects and 7 SAMA chapters were involved in community health activities. In that year, the concept of year-round, locally-funded projects was put into application in Kansas City. The Conference of Student Professional Organizations in Kansas City represented fifteen health science schools working together throughout the year in community service projects. Similar programs were developed in Detroit, New Orleans, and Cleveland.

During the summer of 1968, the most ambitious program ever to be undertaken through student auspices up to that time was initiated. Through grants amounting to over a million dollars supplied largely by the Regional Medical Programs to SHO, 400 health students were placed in communities throughout the country for ten weeks in the summer. The students were to facilitate the provision of health science services to the communities and document the health problems in those communities.

The summer of 1968 was one marked by tremendous strain and conflict. The assassinations of Martin Luther King and Robert Kennedy and the devastating riots that rocked this nation had a profound effect upon the student projects. Racial confrontation exacerbated the already precarious provider-consumer relationships in the communities. Many students found themselves aligned with militant political-action groups which sought to change very basic problems in economics and political power. The complexity and intimate relationship between health problems and the enormous social problems proved very frustrating to the students.

These feelings of frustration and anxiety led to the growth of negativism and nihilism among many of the student participants. At the fourth Annual Assembly of the Student Health Organization held in Philadel-

phia in November, 1968, these feelings were expressed by students as a desire to resign from active community service programs. It was felt that such programs were not valid approaches to the solution of more basic problems. Attention was focused on the burning political issues of the time and on more revolutionary tactics in attaining change.

The Fourth Annual SHO Assembly marked the end of the first era in health student involvement. SHO became a splintered group, turning to radical analysis of the social structure in the nation and abdicating its role as a leader in student activism and participation.

What the SHO had accomplished was an awakening of the sense of commitment on the part of health students to the communities they were to serve. It uncovered the underlying sepsis infecting the sickness in American medical care. We were, indeed, in the midst of a health care crisis.

1968-69 saw the development of extensive local and national student health projects primarily sponsored by the Student American Medical Association. The basic alterations between the SAMA projects and SHO projects involved the goals. Students were no longer viewed as providers of health care to the communities. The role of provider, though extremely ego-satisfying, had produced deleterious effects on the communities in which health programs had been conducted. Primarily, the students were not fully trained professionals; thus the care they provided, though sincerely motivated, was inferior care. This only promulgated the two-class system of health care. Secondly, the care provided by students was discontinuous, lasting only the ten weeks of the summer. The expectations of the community were raised, only to be dashed with reopening of the schools in the fall.

The positive aspects of the SHO programs were preserved in the SAMA program. First, it exposed students to the deficiencies inherent in our present health care delivery system. This realization that all is not well was something new to many students who had been exposed only to selected models through their university curricula. Secondly, it offered students alternative models of health care delivery other than those traditionally taught in schools. It emphasized the need to be responsive to the real needs of the patient served, both as an individual and in relation to his family and community. It impressed upon students the other important factors involved in good health care: namely, socioeconomic and political factors, cultural factors, the importance of preventive health maintenance, manpower utilization and efficiency, and maldistribution of health manpower and resources. Finally, the projects offered the students the ability to work with students of other health disci-

plines as a health team, enabling them to learn how the other disciplines contribute to the better care of the patient.

The first major project developed with these criteria in mind was the Appalachian Student Health Project. This health manpower recruitment program was designed to help correct the problem of maldistribution plaguing the Appalachian region. One hundred and twenty medical, nursing, dental, and pharmacy students spent nine weeks in the summer of 1969 in the Appalachian states. Rather than providing services, the students worked directly with professional preceptors observing the delivery of health care in rural America. In addition, over half of their time was spent outside their preceptor's office or hospital, working in the community, observing the problems of isolated rural areas. Each student worked on a project of his own related to one observed problem. These projects often evolved into sophisticated programs perpetuated by the community after the students had left.

A similar program was initiated in which health science students were placed within Job Corps camps. Another program, the Medical Education and Community Orientation Program (MECO), was started in Illinois but was restricted to medical students in their preclinical years based in a community hospital.

In the summer of 1970, the American Indian Health Project complemented the Appalachian program. This provided an additional dimension of cross-cultural exposure for the students. The Indian Project was particularly innovative in that the students were invited by their respective Indian tribal councils and were directly responsible to these Indian consumer groups. Additionally, the students worked with adolescents from the Neighborhood Youth Corps in interesting them in pursuing health careers.

A new dimension was added in the spring of 1971, signifying the beginning of the third era in community health. At a meeting of the National Student Health Project Coordinating Subcommittee in Atlanta in March, it was decided that in order to have significant impact on the total health manpower development picture in the areas in which students were working, it would be necessary to involve health science schools and other health provider agencies and institutions in a much more meaningful manner. Thus, the goal of student projects would be primarily catalytic, acting to facilitate a coordinated and cooperative approach to fulfilling health manpower and service needs in a community by the community residents themselves, health providers, students, and the agencies and institutions concerned with those projects.

Thus, the National Student Health Project sought to involve the health science schools in the develop-

ment and operation of the programs. An effort was made to persuade the schools to grant academic credit for the student participants. Involvement with local agencies such as Regional Medical Programs was established to make the programs locally administered and year-round. Program objectives included the establishment of local health education centers in the communities in which the students worked which would then become the focus of future program development and health manpower programs.

Current Status

The goal of the student projects to create a "critical mass" of change agents within the educational institutions came to fruition around 1972. Medical schools responded to increasing student pressure by awarding academic credit to preceptorship training and initiating their own programs. The Bureau of Health Manpower in the Department of Health, Education, and Welfare began supporting medical school-initiated preceptorship programs.

In 1972, 46 programs were supported at a funding level of \$2 million. By 1976, the number of programs supported had increased to 67 and the funding level is now over \$6 million. Approximately 5,500 students participate yearly in such preceptorship training programs.⁴

The second article in this series will explore the preceptorship training activities in primary care in Connecticut.

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New Rabies Vaccine is Found Effective

A team of U.S. and Iranian researchers, partially supported by NIH's National Institute of Allergy and Infectious Diseases, has successfully used a new rabies vaccine to treat 45 people bitten by rabid animals. Called a major medical advance, the vaccine is made from rabies virus grown in human cells; it has no side effects and protects with only six injections—making it the first completely effective weapon for protecting man against this generally fatal viral infection.

Once symptoms appear, there is no reliable treatment for rabies. Prompt, post-exposure vaccination can often prevent development of the disease, but not without potentially serious risks. Typically, administration of the current rabies vaccine—grown in duck embryo cells—requires anywhere from 14 to 21 injections—with no guarantee of adequate immunological protection. In addition, some people experience allergic reactions to the foreign animal protein. These side effects range from painful swelling to paralysis and death.

The new vaccine, developed by Dr. Hilary Koprowski and his co-workers at the Wistar Institute of Anatomy and Biology in Philadelphia, is made from rabies virus cultured in WI-38 cells—fetal human lung cells widely used in the production of other vaccines. Results from previous studies indicate that the new human diploid cell vaccine—HDCV—causes virtually no side effects and is highly immunogenic.

Convinced of the vaccine's safety and effectiveness, the investigators in the reported study set out to test HDCV in an area of the world where rabies is a serious problem. Physicians at the Pasteur Institute in Iran collaborated with the U.S. group in using the new vaccine—coupled with antirabies serum—to treat a group of people severely bitten by rabid dogs and wolves between June 1975 and January 1976. As soon as the rabies-exposed victims could be reached, 44 of the 45 were given the antirabies serum for immediate protection. At that time—four to 14 days after exposure—they were also given their first injection of vaccine, followed by five more shots over a three month period.

Six to twelve months after treatment was initiated, the investigators reported that none of the victims developed rabies or experienced any adverse reactions to the vaccine. According to previous rabies statistics, about 35 percent would have died had they not been treated. What is even more striking, say the researchers, is the fact that treatment in some cases was started as late as 14 days after exposure. In the past, such delays have invariably resulted in failure to protect some of the exposed people from rabies death.

Family Practice—A Ten-Year Review

At the 1966 Clinical Convention, the Council on Medical Education presented a report, "Meeting the Challenge of Family Practice," as prepared by an ad hoc committee chaired by William R. Willard, M.D., and including representation from the Council on Medical Education, the American Academy of General Practice (now the American Academy of Family Physicians), the American Medical Association Section on General Practice (now Family and General Practice), and the Association of American Medical Colleges.

The House of Delegates endorsed the report and authorized the Council on Medical Education to develop and initiate plans for its implementation.

The Council on Medical Education wishes to report on progress during the past decade, and on the current status of education for family practice in light of the recommendations of the report of the ad hoc Committee on Education for Family Practice, which has become known as the Willard Report. Since the publication of the original report, numerous actions have been taken to alleviate the shortage of primary care physicians, especially in family practice, internal medicine and pediatrics. The 1966 report was limited to family practice, and this progress report will be similarly limited.

Review of Recommendations of the Report of 1966

The ad hoc Committee on Education for Family Practice recommended that "Major efforts should be instituted promptly to encourage the development of new programs for the education of large numbers of family physicians for the future." The recommended programs would relate to all levels of medical education, including premedical preparation, medical school education, internship and residency training, and continuing medical education. The need for excellence, comparable to programs in other specialties, and for flexibility to permit the design of programs to meet the needs and interest of individual physicians was emphasized.

During the last ten years, little modification has occurred in premedical education in relationship to education for family practice. Education prior to admission to medical school is extremely diversified and premedical advisors are quite varied in their opinions and techniques. Apart from the formal premedical curriculum, physicians in some communities have provided students an opportunity to consider the

challenge and the rewards of a career in family practice. The effectiveness of these efforts is difficult to measure.

Undergraduate Education for Family Practice

Medical schools have responded to the need to educate family physicians. During the past ten years, approximately three-fourths of U.S. medical schools have developed departments or divisions of family practice. Among medical schools with departments or divisions of family practice, there is considerable variation in the degree of emphasis on this new discipline in undergraduate medical education. Some medical schools provide an experience in offices of family physicians for their students. These preceptorships are an integral part of the educational program when the preceptor is a member of the faculty, and the experience augments the clinical clerkships in hospitals.

Career choices are being made by students earlier in their medical school experience. Early exposure to family practice will increase the present interest of students in family practice as a career.

The teaching of family practice as it develops in the medical schools will require a serious and sustained commitment of resources. This commitment will involve financial support, and most of all the full cooperation of the clinical faculty in all the major fields of medicine that are involved in the education of medical students. Medical schools that are not prepared to make such commitments cannot develop sound programs of family practice.

The number of students entering the field is influenced by the strength of the department or division of family practice. Some of the schools that emphasize family practice as a career choice lack family physicians in prominent positions as role models for medical students.

The Willard Report recommended that "medical schools and teaching hospitals should be urged to explore the possibility of developing models of family practice, in cooperation with the practicing profession."

The response to this recommendation has included at least two models for medical students and residents. One is the family practice center that is a critical resource for residency programs. Another model is available to preceptees who work with family physicians in varied types of practice.

Recommendation: The Council on Medical Education recommends that in the future all available data about undergraduate programs in family practice be

accumulated periodically and reported to the House of Delegates. The data should describe the administrative organization for the teaching of family practice, the curriculum, the faculty, facilities and budgetary support.

Graduate Medical Education for Family Practice

The development of residency programs in family practice has been rapid. More than 293 residencies in family practice were approved by July 1976. In the academic year 1975-1976 there were more than 3,700 physicians in family practice residencies, with 1,616 in the first year, 1,262 in the second year, and 842 in the third year. Ninety-six percent of the budgeted first-year positions were filled.

The increasing demand for residency training in family practice will require the creation of new programs and the expansion, where feasible, of current programs. Additional resources will be needed if these programs are to meet the standards for accreditation. The Council on Medical Education is cognizant of the need to expand graduate medical education for family physicians. At the same time there is concern for the quality of the programs. The Residency Review Committee and the Liaison Committee for Graduate Medical Education, which accredits all residency programs, have made a major effort to assure that approved graduate programs meet or exceed the standards. The rapid, and desired, increase in the number of programs has complicated the monitoring of these programs.

The standards ("Essentials") applied in the accreditation of residency programs for family practice are being revised. The basic requirement for comprehensive experience in the major specialties of medicine as they apply to family practice must be retained. It is likely, however, that the structure of programs will change and requirements defining acceptable settings for education for family practice will be modified. It is expected that in the future programs will be designed to permit resident physicians to move easily from other fields into family practice if their interests change to this field of specialization. It is also desirable that residents in family practice who decide to enter a different specialty receive credit for their training in family practice. These developments will have significant effects on graduate medical education in all of the recognized special fields of medicine, including education for family practice.

Recommendations: The Council on Medical Education recommends that the standards ("Essentials") for graduate education programs for family practice be revised to permit greater diversity of education for family practice and to permit residents to more readily change their field of specialization.

It further recommends the use of all available educational resources to improve and to expand graduate medical education in family practice. Formal affiliation agreements among hospitals that offer approved residency programs, and between these hospitals and other institutions that provide medical and health care, should be developed.

Continuing Medical Education for Family Practice

Although programs of continuing education for practicing physicians have been widely available during the last ten years, administrative units of family practice in the medical schools and teaching hospitals should develop the ability to provide continuing education for family practitioners in their areas. Research in patient care delivery systems and a response to the need for a continuing update in the medical knowledge of the practicing physician are well within the capability of some of the newly developed departments of family practice. As techniques for the analysis of profiles of practice and for self assessment become increasingly available, those who teach family practice can provide continuing medical education directed to the educational needs of individual physicians.

Recommendation: The Council on Medical Education recommends that present programs of continuing education for family practitioners be continued and strengthened.

Financing of Education for Family Practice

The Willard Report states: "New sources of financial assistance should be developed for the support of family practice teaching programs. Substantial funds should be made available for all aspects of the programs, including the conduct of the educational program, the recruitment and training of full-time faculty, the development of facilities and models of family practice, and the conduct of research in patient care and community medicine."

It should be recognized that the resources for all aspects of medical education are finite and that there has been increasing pressure on these resources. Nevertheless, numerous sources of federal, state and private funds have become available for various phases of family practice teaching. Some of these funds are shared with other specialties in the development of further primary care training, especially pediatrics and internal medicine.

Much of the funding, particularly from federal programs and private foundations, has been designed to assist in developing programs of education for family practice, but not to sustain established programs. It is difficult for some medical schools and for some hospitals that have created educational programs for family practice to obtain funds to maintain and expand these

programs. The difficulty results in part from the need for an educational experience involving ambulatory patients. Reimbursement for the cost of ambulatory care has not been available to the extent that reimbursement is available for the care of hospitalized patients. Since financial support is essential to maintain the quality as well as the operation of programs of family practice, financial support for these programs has become a significant item in the budgets of medical schools, hospitals and ambulatory care centers. It will be necessary to reassess priorities and reallocate funds if adequate funding is to be available for teaching family practice at the undergraduate and graduate levels.

The percentage of graduates of U.S. medical schools entering primary care specialties now exceeds the goal established in Board of Trustees Report, 1973 as adopted by the House of Delegates. As the number of students graduating from U.S. medical schools increases, the number of funded positions in residencies in primary care must also increase if the students seeking such positions are to be able to enter the primary care fields. Support for the care of ambulatory patients becomes increasingly important, as does the development of capital to build new facilities and to renovate and expand existing facilities for ambulatory care. It should be recognized that large numbers of patients receive care from residents who learn through the provision of medical services to patients. For example, it is estimated that as an essential part of their education, residents in family practice within the next few years will provide care for approximately 4.5 million patients if present trends continue and if adequate financial support of residencies in family practice is available.

The growth of family practice residencies has been limited by the availability of potential faculty to conduct programs of high quality. Private practitioners have contributed significantly to these educational programs but their efforts may be limited in those medical schools that continue their long-standing policies with respect to academic appointments. Practice experience is an essential element for a teacher in this discipline, as is adequate financial support. Although not all who complete family practice residencies subsequently practice in shortage or rural areas, it is believed that many do.

Recommendation: The Council on Medical Education recommends that the American Medical Association encourage the availability of adequate financial resources, preferably from multiple sources, for the development and expansion of educational programs in family practice and for improving the quality of these programs.

Recognition of the Specialty of Family Medicine

The 1966 report recommended: "Recognition and status equivalent to other medical specialties should be given to family practice. An appropriate system of specialty certification should be provided for those who have completed approved educational programs and have demonstrated their competence as family physicians. The graduate program (i.e., internship-residency program) should be an integrated whole, evaluated for accreditation by one body rather than two."

This recommendation appears to have been accomplished by the establishment of a certifying body, The American Board of Family Practice. The graduate educational program, i.e., internship and residency, has been integrated into a three-year training program which is evaluated by the Residency Review Committee for Family Practice and accredited by the Liaison Committee on Graduate Medical Education.

The Council on Medical Education recognizes that the role of family physicians in the care of hospitalized patients, and the eligibility of family physicians to be paid for these services, are important for the recognition of this specialty. These matters, as well as the issues which surround professional liability and their influence on the availability of medical services, are undergoing transition. Although these issues are not primarily educational and therefore do not fall within the purview of the Council on Medical Education, the Council feels obliged to call attention to the profound influence they exert on both medical education and the choice of careers by students.

Resolution of these issues will influence the future recognition of the family physician and his ability to serve his patients.

The Willard Report states: "Careful attention should be given to other factors which should make the environment for family practice more favorable and serve as incentives to medical students and young physicians to enter this field."

A favorable climate for family practice has numerous elements, some of which are not within the scope of this document.

Recognition of the practice of family medicine has greatly improved during the past ten years. Many changes have increased the ability of family physicians to deliver more comprehensive primary care to patients: the growing group practice movement, improved transportation of patients, emergency medical service, widespread continuing education efforts through out-research programs of some medical schools and other continuing education programs, and the creation of new allied health professionals to aid in the delivery of care.

Both the public and the medical profession should be aware of the contributions made by family physicians in the provision of medical services. They should also be aware of the requirements of family physicians to function effectively in the provision of medical care. The educational programs for residents in family practice stress the contribution of other medical specialties, of nursing, of the allied health professions and of community agencies in providing essential services to families. The experiences of residents in using community and professional resources to improve the health of patients should have a beneficial effect on medical and health care in the future, but only if there is adequate awareness of the need for these varied resources.

Recommendation: The Council on Medical Education recommends reaffirmation of the importance of a favorable environment for the effective utilization of specialists in family practice, and for the recognition of family practice as a specialty.

The Willard Report recommended: "Careful study should be made of the effect of premedical programs and the admissions procedures, curricula and student evaluation policies of medical schools upon the production of family physicians."

Although numerous studies have attempted to identify factors influencing the student's choice of a specialty, and the characteristics of those who choose various specialties, none have been conclusive.

It is a fact that increasing numbers of recent medical school graduates are seeking residencies in family practice. It is believed that the public, medical school faculties, and an increasing number of medical students now recognize the need for more family physicians. Presumably the factors influencing an increasing number of medical students to choose residencies for family practice are both numerous and

complex. Some of these influences have been noted in this report but the definition of others will necessitate further study.

Recommendation: The Council on Medical Education recommends reaffirmation of this recommendation of the Willard Report.

Summary

This report of the Council on Medical Education reviews the changes which have occurred over the decade since the report "Meeting the Challenge of Family Practice" was issued in 1966. The changes have been rapid and significant. The recommendations of the report have been followed to a considerable degree and have influenced medical education at all levels.

The Council on Medical Education has made further recommendations with respect to periodic reports on the progress of education for family practice in medical schools. It has also recommended that the standards for accreditation of residency programs in graduate medical education be modified to encourage greater diversity in those programs and to encourage cooperation between institutions. These changes should encourage programs of high quality and contribute new resources to sustain and improve education for family practice. This report calls attention to the many factors which influence family practice and have implications for the education of family physicians. The importance of a continuing analysis of trends in medical education, its content and its financing is recognized.

The Council on Medical Education continues its support of and will continue to monitor progress in education for primary medical care of which family practice is an integral and essential part.

Geriatric Medicine: The Necessities

Robert N. Butler, M.D.

Thanks to scientific and social advances more Americans are living longer. We are in the midst of a demographic revolution. Today, 23 million Americans are aged 65 and older—10 percent of the population—a segment which is expected to increase by 50 percent in the next three decades.

In light of these facts, it is ironic that even though the word “geriatrics” was coined in 1909 by Ignaz Nascher, an American, we have barely gone beyond incorporating it into our vocabularies since then.

There is no great center of geriatric medicine in the United States. Only recently has the first endowed chair in geriatric medicine been established, at the New York Hospital-Cornell Medical Center. We do not offer fundamental education in geriatric medicine to our doctors: a 1970 survey of 99 medical schools found that 50 made no mention of geriatrics in any form (Freeman)¹ and, of the nation's 114 medical schools, only 45 offer electives in gerontology (AAMC, 1976).

The medical profession is ill prepared to meet the demands that this will place on our health care system. As a member of the medical community, I speak from within the family. There may be no conspiracy to deny proper health care to the elderly, but neglect does happen in society as a whole and in the medical profession in particular. “Ageism,” the pervasive negative attitude toward aging, can be traced from the classroom to the consulting room.

Today, not tomorrow, is the time to prepare for the coming shift in age of our population. The logical place to start is in our medical schools, where the future of medical practice and the attitudes of practitioners are shaped. Expressions of concern and interest have come from individuals, professional groups, some medical schools, and the students. A significant example on the subject comes from the Council of Medical Education² of the American Medical Association:

It is appropriate that the subject of geriatric medicine be included in the curriculum of all American medical schools. It should not be overlooked that in contrast to essentially all of the other subjects for which special teaching emphasis has been sought, the aging process involves every person and every patient. It is suggested . . . that there be established at each medical school some unit upon which responsi-

bility for teaching and research in geriatric medicine could be focused. The development of such units would be enhanced greatly were the National Institute on Aging able to provide teaching and training as well as research grants. Such units would most likely be established within departments of medicine or family medicine.

(Council, 1976)

The medical community itself has also expressed concern. When surveyed, 75 percent of the practicing physicians questioned answered “yes” to the question: “Do M.D.s need special training in geriatrics?” (*IMPACT*, 1976).

The establishment of the National Institute on Aging represents Congress' awareness of the need for greater scientific concern for the process and problems of aging. The Institute was created to conduct and support biomedical, social, and behavioral research and training related to the aging process and the diseases and other special problems of older Americans.

The question to be debated is not whether geriatric medicine should be a specialty, certified or otherwise. Rather, the question is how can we expose every physician to the procedures of primary care necessary to deal with older patients? The body of knowledge required for treatment of older people is not just disease-categorical; it is broad in perspective and in keeping with the complex character of human experience. It includes the multiple physical, personal, and social processes that occur with age.

From the Institute's perspective, the teaching of geriatric medicine is necessary to catalyze the research upon which an effective service delivery system can be based. By expanding our knowledge of human aging, we will ultimately enhance the quality of life during the later years and help alleviate the heavy financial and emotional pressures placed upon the middle aged and younger generations by the responsibility of caring for the old. These research efforts will also help to reduce our massive national health expenditures, many of which are associated with the disabilities and diseases of old age.

Arguments in support of the teaching of geriatric medicine are based on five compelling necessities—intellectual, demographic, epidemiological, economic, and attitudinal.

Intellectual

As a practical matter, the first argument for the teaching of geriatric medicine in schools of medicine

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is that this body of special knowledge already exists. It is far from complete, but nonetheless, it is substantial.

The data that underpin geriatric medicine are to be found in the disciplines of human physiology and pathophysiology. These data deal with the differentiation of time-related changes from pathogenetic elements, from the results of socioeconomic adversities, and from the effects of personal crises. The characteristics of changes inherent in later life can be distinguished from the concomitant crush of environmental events. Making these distinctions is the first critical step in recognizing, diagnosing and ameliorating conditions that are not irreversible.

With time comes an accumulation of long-term diseases, such as arteriosclerosis, and disabilities, such as joint trauma. In the later years, multiple disorders are present as the body's protective mechanisms are compromised. Symptoms present differently in the old, and the inadequately trained clinician can miss diagnoses. For example:

An older person with hyperthyroidism may appear apathetic, not hyperative.

Tuberculosis may proceed in silence.

Appendicitis may occur without the characteristic abdominal tenderness at McBurney's point, without fever, and without an elevated white count.

An older person may have a heart attack without chest pain and may instead appear confused and disoriented, seeming to be the victim of a stroke.

Demographic

The second argument for the teaching of geriatric medicine is demographic. People 65 and older constituted three percent of the American population in 1900; they made up 10 percent by the time of the Second White House Conference on Aging in 1971; will perhaps be 12 percent by the turn of the century; and may reach some 17 percent between 2020 and 2030. The latter figures are predicted upon the highly unlikely assumptions that there will be no improvements in the delivery of health care, nor achievements in scientific research. It is far more probable that in 2020, one out of every five Americans will be over 65.

Epidemiological

The third reason for including geriatric medicine in the medical school curriculum is epidemiological. If we are to have a responsive, high quality health care system, we must first accurately and realistically measure the proportions of the problems with which we are confronted. For example, we must identify and face the high incidence and prevalence of disorders that accumulate or develop for the first time in the later years. One of these is senile dementia—so devas-

tating to human personality, identity and memory and the reason why an estimated 50 percent of patients enter nursing homes. Diabetes, rheumatoid arthritis, osteoporosis, cardiovascular and cerebrovascular diseases, and many more require accurate delineation and epidemiological analysis to enable the health care system to respond effectively.

Economic

The fourth argument for attention to geriatric medicine rests on economics. The national expenditure on health in 1976 amounted to 139.6 billion. Of that staggering figure, about half (\$60 billion) was in expenditures for chronic disease. One-third of all acute hospital beds were occupied by older people. There were 1.2 million patients in the country's 23,000 nursing homes in 1975—more patients than in the 7,500 voluntary hospitals—and nearly one-fourth of all drugs consumed in the nation were taken by older Americans.

Haphazard service delivery, resulting from incompletely trained diagnosticians and technicians, is expensive. Without a thoroughly educated and sensitized corps of physicians and supporting service delivery personnel, new ideas will not germinate; research loses its momentum; and health care systems stagnate. Measures that can save time and money as well as lives cease to find their way into use.

Attitudinal

Failure to provide adequately for older people may grow out of an attitudinal problem, one that surely should be counteracted by the sensitive teaching of geriatric medicine. Americans in general suffer from a personal and institutionalized prejudice against older people. It is a cultural insensibility that could be changed through study, education, and understanding.

The attitudes of physicians toward their profession and their patients are largely shaped in medical school. It is here that future doctors frequently encounter a negative influence on their approach to the aged. A study (Spence³, 1968) of University of California medical students showed that their attitude toward older people actually deteriorated during their four years in medical school.

Medical students are not brought into contact with healthy older people in the same way that they are exposed to healthy children, for example, in sunny well-baby nurseries and clinics. In fact, there is no medical school in the country that routinely and systematically rotates students through community senior centers. One wonders whether medical students would choose to be pediatricians if, during their train-

ing, they saw only babies suffering from irreversible conditions.

Conclusion

One should not ignore the contention of medical school deans that they already have an overcrowded curriculum and, therefore, no room for geriatric medicine. But those arguments have been heard in the past; yet such new developments in science as neonatology and nuclear medicine somehow found places in the teaching program.

In the later analysis, no medical school has ever taught all that might or could be taught. What is essential is that physicians of the future develop an understanding of the continuum of the life process, realizing that the later stages are no less demanding, or deserving, of their scientific and humanitarian attention.

The area of geriatric medicine is one of the primary concerns of the Institute. Although our Congressional mandate does not permit us to train physicians in geriatric medicine, we can focus attention on this area of need and cooperate with those in the health field

who are able to support training. We intend to sponsor conferences related to geriatric medicine and research alone and in conjunction with the American Geriatrics Society and others. The Institute also will explore the legislative authority to support post-doctoral training in geriatric medicine and to consider research centers in medical schools.

Solutions to what has come to be mistakenly called the "problem" of aging can be found through a collaboration between research scientists and practitioners in the field. The Institute intends to serve both in the interests of the elderly and the nation as a whole. What an achievement it would be if the United States, the nation that gave birth to the father of geriatric medicine, could become a leader in the field.

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Memory and the Aged

Contrary to the prevailing belief that memory declines with age, complaints of memory impairment in the aged may be associated with depression rather than actual memory performance, according to a study funded by the National Institute of Mental Health of HEW's Alcohol, Drug Abuse, and Mental Health Administration.

The study was conducted by Robert L. Kahn, Ph.D., Associate Professor of Psychiatry and Human Development of the University of Chicago.

Dr. Kahn suggests that memory complaints and actual performance depend on the interaction of depression and diminished brain function. Among those elderly persons with normal brain function, severe depression will tend to lead to exaggeration of the complaint, while in those with altered brain function and low depression, the complaint will be minimized.

During the course of the study, 153 persons, ranging in age from 50 to 91 with a mean of 65.1 years, were evaluated in the Gerontology Clinic outpatient unit of the University of Chicago Department of Psychiatry. Subjects included patients referred from the psychiatric outpatient unit, psychiatric inpatients, and a number of subjects—spouses, siblings, children, parents—who participated as collaterals of the patient group. Since a number of persons in all three groups showed degrees of depression and brain dysfunction,

subjects were classified according to their functioning in clinical analysis.

A battery of tests conducted during interviews with the subjects showed little correlation between complaint about memory and actual memory function. In contrast, significant correlations were found between memory complaint and depression. Among both the normal brain function group and the altered brain function group, subjects who were more depressed had greater complaints about memory. In some instances, those who complained about their memories actually functioned better than those who did not. Among the subjects who showed a high degree of depression, those with normal brain function complained as much about memory as those with altered brain function, even though the latter had a far greater difficulty on the memory procedures.

Some of the tests included in the study were: the Hamilton Rating Scale for Depression and an Adjective Mood Checklist derived from McNair and Lorr for determination of affective condition; the Face-Hand Test and the Mental Status Questionnaire to evaluate brain function; and the Digit Span, the Babcock Story Recall Test, paired associates learning tasks and a variety of tests based upon personal life-events and general occurrences to test primary, secondary, and tertiary memory.

Drug Information Center—A Rapid Source for Therapeutic Information

Moses S. S. Chow, Pharm. D.

It has been estimated that the biomedical information doubles every 15 years!¹ This rapid rate of increase has virtually resulted in an information "explosion" and makes it extremely difficult for the physician to keep up with the current therapeutic information from all the published journals and textbooks. While many physicians can easily obtain certain current drug information from the detailman, such information is likely to be biased.² There is no doubt a need for a convenient source to provide accurate and objective information.

There are now more than 70 drug information centers in the United States as compared to one in 1962.³ These centers usually have specific drug data files and utilize Iowa Drug Information System and/or de Haen Drug Information Systems for rapid retrieval of information. Many of these centers are also staffed by pharmacists with an advanced degree, e.g., Doctor of Pharmacy (Pharm. D.) with post graduate clinical training.³ These centers can provide specific or general drug information rapidly, accurately, and concisely to meet the needs of health practitioners. Some drug information centers also act as poison control centers. Most of the centers also review drugs for the hospital committees and publish newsletters.

The unique feature of the modern drug information center is its accessibility as well as its ability to provide patient specific drug information and consultation for the clinicians. An example is the Hartford Hospital Drug Information Center (HHDIC), where the majority of the patient specific drug information are from personal contact. Approximately 84% of all the drug information and consultations are provided to the physicians. The most frequent categories of information provided are drug therapy (e.g., drug of choice for a particular situation), drug-induced disease or adverse reactions, dosage, general pharmacology, and pharmacokinetic data (e.g., half-life of drugs). Other categories of information include drug interactions, I.V. solution incompatibilities, foreign drug identification, availability of drug, and drug overdose information. Much of the information require a judgment by the drug information staff after evaluation of the patient status and the available literature information. Interestingly, the Physician's Desk Reference and FDA Drug Bulletin, which are used most frequently by the physicians,⁴ are not the most frequently con-

sulted source by the drug information center staff. Overall, journals are the most frequently used reference by the drug information staff.

Table 1
DRUG INFORMATION AND POISON INFORMATION CENTERS IN
CONNECTICUT

Hartford Hospital Drug Information Center (524-2221) (service available to the Hospital staff only)
Yale-New Haven Hospital Drug Information Center (436-4880) (service available to the Hospital staff only)
University of Connecticut Health Center Drug Information (674-2783) (service available to all health practitioners within the State)
University of Connecticut Health Center Poison Information Center (674-3456) (service available to everyone in the State of Connecticut)

In addition to providing objective drug information, pharmacokinetic consultation is also a part of the daily activity of the HHDIC. This consultation is primarily concerned with estimation of plasma levels of potent drugs as well as calculation of individualized dosage regimens for the patient. For example, the drug information staff might be asked to calculate the dosage of gentamicin to achieve a maximum level of 8 ug/ml and a minimum level of 1.5 ug/ml (right before the next dose) for a 100 kg patient who is on hemodialysis every two days. The utility of such consultation is to provide more precise drug therapy in unusual situations in which nomograms for adjustment of drug dosages are not available.

Other activities of the Hartford Hospital Drug Information Center include reviewing drugs for formulary additions and reporting unusual adverse drug reactions to the Therapeutic Committee. The Center also publishes a bimonthly newsletter for the hospital staff.

Although the scope of service provided by each drug information center may vary, the ultimate aim of all drug information centers is to improve patient care by providing specific drug information and by promoting rational drug therapy. As a whole, drug information service is a unique modern pharmaceutical service and should ideally be available in all hospitals.

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Month in Washington

The Congress has received its first major health bill from the Carter Administration—a massive and complicated program for limiting hospital revenues to a nine or ten percent rise annually. Income from all inpatients, private as well as federal beneficiaries, would be affected.

Hospitals exceeding the allowable increase could be socked with a penalty tax amounting to 150 percent of the “overcharges”. Such offenders also would have to reduce charges the following year.

Physicians’ offices were not affected by the proposed legislation, though Health, Education and Welfare Secretary Joseph Califano has indicated this is under study.

The hospital plan received the fanfare of a White House send-off, with a statement by President Carter and White House briefings of affected groups and of reporters. Contrary to some expectations, Carter did not use the plan as the keystone of a major health message to Congress, though he mentioned national health insurance.

“Unrestrained health costs also restrict our ability to plan necessary improvements in our health care system,” Carter said. “I am determined, for example, to phase in a workable program of national health insurance. But with current inflation, the cost of any national health insurance program the Administration and the Congress will develop will double in just five years.”

Congressional hearings are expected to open in a few weeks on the hospital program. There’s no way the proposal will get through Congress unscathed, experts believe. The lawmakers have been pushing to brake the costs of Medicare and Medicaid, but a cost-control program involving an entire private industry is a different matter. There is almost no sentiment in Congress for a revival of wage-price controls for the economy as a whole.

At the insistence of organized labor, the proposal contains an exemption for hospital wage increases which by itself would appear to blow the nine percent restraint out of the water. A hospital could adjust upward its permissible revenue by the amount of any wage increase.

Inpatient revenues of the 6,000 acute-care hospitals in this country are covered. Brand new hospitals, federal hospitals, and hospitals controlled by Health Maintenance Organizations (HMO’s) would be exempt.

The legislation also imposes a limit on new capital expenditures, fixing a national level for such expendi-

tures below that of recent years and allocating new capital spending among the states by formula. With the assistance of local planning agencies, each state would determine how the hospitals can make capital expenditures.

States which operate cost containment programs which are capable of meeting the federal criteria could continue their own regulatory approaches.

President Carter said his program will save about two billion dollars in fiscal year 1978—starting next October. This would work out to over \$650 million in the federal budget, over \$300 million in state and local budgets, and almost \$900 million in private health insurance and payments by individuals. In fiscal year 1980, total savings were put at \$5.5 billion.

The American Hospital Association charged that the control measure “would severely jeopardize the provision of hospital care to the American public.” Hospitals and physicians will unite in opposing it, the AHA said.

“This proposal would not only prevent hospitals from increasing services to patients, it would require some to cut back existing services,” said J. Alexander McMahon, President of the AHA, at a Washington, D.C. news conference.

“The real victims would be the sick and injured, and for their sake, hospitals across the country will unite to oppose this bill.”

McMahon said the Administration’s proposal is “extremely complicated and would require a huge bureaucracy to enforce it, further adding to hospital costs.” He predicted flatly that Congress would reject the plan.

American Medical Association Executive Vice President, James H. Sammons, M.D. said that while he could not comment in detail on the President’s proposal without study that “the medical profession must be concerned about the impact that this concentration on expenditures will have on the quality and availability of hospital care for the American people.”

Walter J. McNerney, President of the Blue Cross Association, said a program to limit the rate of increase in revenues on any segment of the health care industry, whether hospitals or other providers, ought to be designed not only to moderate cost increases but, equally important, to provide incentives for more efficiency within the established revenue restrictions.” He urged greater flexibility.

Michael Bromberg, Director of the Federation of American Hospitals (FAH) said the proposal “is unfair and arbitrary and it will not work. Not only is it impossible to inhibit inflation by law, but there is a real danger that by legislating a ceiling on hospital

costs, the Administration would be directing hospitals to cut back on the quality of health care delivery," he said.

As Carter described his plan, "This legislation is not a wage-price control program. It places no restrictions on the hospital's ability to determine its charges for any particular services. It places no limit on the size of any wage demand or settlement. The program establishes an overall limit on the rate of increase in reimbursements, permitting doctors and hospital administrators to allocate their own resources efficiently, responding to local needs and individual circumstances."

The cost containment system is "intended to flow directly into a long-term prospective reimbursement system," said Carter. Congress and the Administration are already at work on this long-range system, he added.

Under the bill, the basic limit on increases in total inpatient-care revenues would be set by a formula reflecting general price trends in the economy as a whole, plus an additional amount to accommodate some increase in intensity of patient services.

A crucial vote is coming soon on legislation to arm the Federal Trade Commission with strong new powers over business and to expand its authority over non-profit groups including medical associations.

The full House Commerce Committee will be taking up a bill approved recently by the Subcommittee on Consumer Protection. The issue pits consumer against business interests with important implications for the medical community.

The FTC has been very active for more than a year in the medical field, taking actions against medical ethical advertising codes, relative value scales, anti-trust inquiries about possible resistance to Health Maintenance Organizations (HMO's), challenging the validity of professional accreditation, among other moves.

Heretofore, the Agency has not had the power to act against non-profit associations without contending that it is dealing with aspects that are essentially commercial. The bill before the House Commerce Committees would for the first time make non-profit, professional groups a clear responsibility of FTC.

The American Medical Association has urged that non-profit organizations not be placed under FTC control.

Testifying against the legislation (H.R. 3816), former Federal Communications Commissioner Newton Minow, speaking for the AMA, warned Congress that an FTC battle could devastate non-profit groups.

"A host of diverse organizations having little or no

impact on our economy would become subject to the regulatory jurisdiction of the Commission if this provision is adopted," said Minow. "Organizations such as the Boy Scouts of America, the Democratic National Committee, the National Association for the Advancement of Colored People or the United Fund could suddenly find themselves targets of an FTC investigation . . ."

Under H.R. 3816, the FTC could seize the assets and records of non-profit associations, and levy fines up to \$5,000 per day. The AMA warned that this extreme power was being granted, not to the normal repository of such authority—the judiciary—but rather to a federal agency.

"The cumulative effect to the vast punitive powers and resources of the FTC would cause all but the most well financed organizations to succumb to FTC pressures and demands," Minow said. "It is difficult enough for large business corporations, which can pass such costs on to their customers, to do battle with the government. But for a not-for-profit charitable, scientific or educational organization such a battle can be totally devastating. The ends of justice are not served where vindication also means bankruptcy."

Mr. Minow also warned that charities subjected to such treatment would be hardpressed and would be forced to rechannel funds from humanitarian directions to legal protection.

Minow cautioned that the proposed extension of FTC authority would ultimately work against the public interest.

"Professional societies are continually exhorted to exercise more supervision and regulation over the conduct of their members. The Commission, however, would release these individuals from the ethical structures of professional associations and subject the public to action based upon the unrestrained ingenuity of individual professionals with only the government able to guard against any excess."

The short and unhappy bureaucratic life of Christopher Fordham, M.D. has been concluded in a policy dispute with HEW Secretary Joseph Califano. Dr. Fordham, designated to be the Assistant HEW Secretary for Health spent several weeks on the job before deciding he had had enough. The physician returned to the University of North Carolina where he heads the medical school.

Dr. Fordham's decision to leave rocked the Washington health establishment and the HEW Department. Fordham concluded the Assistant Secretaryship had been stripped of authority and that others in the Department, especially Califano, would be calling the shots on health-policy matters.

Reflections from the Dean's Office

Robert U. Massey, M.D.

Recently during a short flight on a southwestern airline, the pilot asked how many of us believed that there was really an energy crisis. He said we could tell him on the way out of the airplane. As I waited near the exit, I overheard him talking with the passengers. It was evident that he believed that energy supplies were plentiful, and that the so-called crisis was some kind of conspiracy.

In his view it was not real, and from his standpoint, he was right. There is no shortage of energy; allowing for variations in cloud cover the same amount falls upon the earth's surface each day, and carbon released by oxidation is repackaged by photosynthesis in many usable forms. Using it is only a matter of technology, production, transporting, marketing, and international politics. All of these are man-made, artificial, and hence, not real. If we need energy, we have only to brush aside profits and politics to find that the supply is limitless. History is a series of conspiracies to deny to some what is lavished upon others.

Undoubtedly there have been conspiracies in history, and powers bent upon evil have accomplished their ends by deliberate planning and careful execution. More often events have occurred which look like conspiracies but are only the result of planning with insufficient information. Good judgment and good intentions do, in fact, often lead astray. Physicians should know that better than anyone.

The danger in attributing conspiracy when events go wrong is that our instincts for vengeance are thereby aroused. We spend our efforts searching for conspirators to bring to judgment rather than finding solutions to the problem.

The crisis in health care is not unlike the energy crisis. It is either real or artificial depending on our view of the world and of history. The energy crisis may be formulated in simpler terms and lends itself more easily to quantitative definitions. Health, sickness, and the cost of medical care are complicated, elusive, and without clear definition, capable of arousing the most intense emotions in usually phlegmatic people. It is easy to see that someone must be to blame, and since there are many who could be, the quest for vengeance becomes part of the search for solutions, and most proposals seem to carry a little punishment for someone.

We are not agreed on the nature of the crisis in health care. Quality does not seem to be the issue for most. "Three-quarters to four-fifths of the population, depending on the survey, are satisfied with their doctors and the care they give; but one-third to two-thirds think the system that produces these results is in bad shape," writes Aaron Wildavsky, and he adds, "That's the trouble: everyone behaves reasonably; it is only the systemic effects of all this reasonable behavior that are unreasonable."¹

Cost may be the most important issue. The working poor cannot afford most kinds of health care, and industrial leaders are worried about the cost of health insurance premiums. Politicians see the market forces working poorly to control health costs, and the bureaucrats in the Federal Trade Commission want to fix that by stimulating competition; the regulators want to put a cap on services.

Our failure to provide equal access to health care is a problem which has not been solved. There are economic and geographic barriers, and for some of our people essential health services are practically unavailable.

There are those who say we have become unfeeling technicians and have lost our humanity; others view medicine as a business, conducted for profit. A few have gone so far as to claim that medicine produces more disease and suffering than it relieves. Theirs is a manifestation of a prevailing antisocialism characteristic of America and growing in our time.

It is tempting to believe there are conspirators on both sides of the issues: a plan to pull down the house of medicine by some; on the other side, a scheme by organized medicine to gain ever increasing profits and power.

The crisis is real enough, although artificial in our pilot's view. He would not be able to see why all of this might not be cut through so that we could get about caring for the sick and preventing disease.

In a sense he is right. We shall not get the answers right, however, until we stop believing in conspiracies.

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EDITORIALS

Coronary Bypass Surgery

Surgical therapy for coronary heart disease continues to generate considerable controversy. The employment of a new therapy without adequate preliminary scientific evaluation is sure to engender this type of debate, and aorto-coronary bypass grafting is simply following the predictable rules of medical science. Nevertheless, medical history is replete with similar endeavors that are now accepted forms of therapy, acceptance gained by the test of time rather than double-blind prospective studies. The reports from Yale-New Haven in this and the July issue of *Connecticut Medicine* add considerable comfort to the forces supporting aggressive employment of aorto-coronary bypass grafting for stenotic coronary disease.

The experience in New Haven over the last several years indicates that patients with angina pectoris can be adequately classified for surgery, and can be presented with detailed data regarding surgical risk. It is salutary that mortality associated with aorto-coronary bypass grafting is now sufficiently low that the patient can view it as an acceptable form of treatment, as compared with non-surgical treatment. It is imperative that other surgical groups, within the state and region, use a similar data collection and reporting system. Patients and their physicians require accountability from all surgical teams attempting to treat coronary heart disease, a disorder whose non-surgical natural history and expected yearly mortality is reasonably well defined.

Several large questions remain to be answered before the place of aorto-coronary bypass grafting is secure on the medical scene. It is evident that the overwhelming number of patients who have good results are enthusiastic about their surgery. Indeed, even

more than some of the most aggressive surgeons, the patients have become the "prophets" of this treatment. Cardiologists familiar with the "born again" reactions of patients who have been subject to such various procedures as permanent pacemaker insertion, prosthetic valve placement, and now bypass grafting, are entitled to demand that we not depend on subjective reports, and that we continue prospective studies employing objective methodology for the long-term assessment of the benefits as well as the risks of surgical therapy. The role of "magical thinking" in patients who have undergone a "trial by surgery" must never be overlooked in understanding their assessment of its benefits.

On the other side of the coin, while three indications for aorto-coronary bypass grafting are widely accepted (symptomatic left main lesions, angina patients refractory to medical therapy, and patients presenting with pre-infarction syndrome), surgical indications in the large number of patients not so classified, but who have severe angiographically demonstrated lesions, are clearly unresolved. While little doubt remains that the operation relieves refractory angina by some mechanism, the question of whether prophylactic graft placement will prevent myocardial infarction (thus preserving more viable muscle and presumably extending life by preventing sudden cardiac death) is unanswered despite the large number of physician adherents to such a notion. Even the supposedly answered question of bypassing a single lesion is not answered adequately, since for most patients the concerns are not only with mortality (for which surgical and medical therapy both offer similar low mortality for single vessel disease) but rather with *morbidity*. Is it better to avoid surgery for a single vessel lesion and risk having a myocardial infarction, when for the same general small risk one can schedule

a surgical approach and possibly alleviate the disorder?

In the patient population presenting with unstable angina, a significant unanswered question relates to the role of coronary artery spasm in the genesis and continuation of this disorder. Studies from abroad suggest that as many as twenty to thirty percent of patients with rest angina experience coronary arterial spasm,¹ and only a small percentage have the typical electrocardiographic pattern of anterior or inferior "variant angina". The development of new pharmacologic treatment for coronary artery spasm² may markedly reduce the number of patients whose pain cannot be alleviated by medical means when unstable angina is the presenting problem. Thus, the study and surgical treatment of patients with unstable angina may undergo remarkable change in the very near future. Employment of a more elective diagnostic and surgical approach may permit a more adequate determination of the real benefit of surgical therapy in such patients. It is interesting to note that in one small study conducted in a prospective random fashion, the only long-term difference in the surgically versus medically treated groups of patients with unstable angina lay in the subjective "quality of life" improvement experienced by the surgical group. It is fair to say that improving the quality of life, whether it be by surgery, drugs, hypnosis, or auto-suggestion, is not to be denigrated as a goal of therapy. The plea of those demanding more scientific support for surgical therapy is simply that we face facts honestly.

It is hoped that these reports on surgical therapy for coronary disease in New Haven indicating the acceptable low risk of this procedure at the present time will be followed by equally careful documentation of long-term benefits.

Alfred L. Aronson, M.D.

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EMS Systems Justification—The Need for CSMS and State Government Support

It is time that the Connecticut State Medical Society gives the authority of its voice to the open support of Emergency Medical Services (EMS) and prehospital emergency medical care.

It is time to ask why the State of Connecticut has not lent adequate financial support to a program of medical care that potentially affects every citizen in the State, a program which was made law, one of the first in the country, by the Connecticut Legislature in 1974 (P.A. 74-305).

That law, sweeping in scope, established an Office of Emergency Medical Services and area-wide EMS Councils to help the citizen gain rapid access to well-trained first responders and to upgrade emergency medical care. It recognized the need to educate the citizen to prevent medical emergencies; to make known the risks and symptoms of myocardial infarction and make it possible for citizens to help in the presence of a medical emergency by intervening rapidly, confidently, responsibly. It recommended the centralized dispatch of emergency medical care; required minimum equipment standards, accountability, and the offering of training to upgrade the emergency care capabilities of first responders and health professionals. It required categorization of hospitals and other facilities as to their institutional capabilities and resources to render emergency medical care to patients having complex illness or injury such as burns, multiple system trauma, severe cardiac conditions, distressed neonates, spinal cord injuries, psychiatric disturbances and poisonings.

It is now apparent that most of the 500,000 people who die suddenly outside the hospital each year, die of cardiac arrhythmias and not of coronary occlusions.¹ That traumatized patients may also develop abnormal cardiac rhythms has also been reported by Lambrew and others.^{2,3} To deal with the urgency and threat to life of such situations, the National Research Council and the American Heart Association have recommended Standards for the delivery of Basic and Advanced Cardiac Life Support^{4,5} and the development of area-wide integrated emergency care programs.

Those programs prepare communities to support life promptly through cardiopulmonary resuscitation (CPR) and facilitate access to personnel trained in airway control, effective patient oxygenation, management of threatening arrhythmias and relief of pain, all under hospital supervision.

Such integrated programs now exist in Jacksonville, Florida; Seattle, Washington; Charlottesville, Virginia and Nassau County, New York, among others. In Connecticut, Advanced Life Support Programs exist in Waterbury and East Hartford and will soon begin in New Haven. Evidence of the effect of such systems are now becoming apparent.⁶

Lund⁷ has shown that 61% of 59 patients with cardiac arrest survived to be discharged from the hospital when cardiopulmonary resuscitation was begun with-

in one minute. This report confirms the importance of prompt basic life support by the citizens.

Grace⁸ and others have reported an 8% mortality in patients, with proven myocardial infarctions, who were seen and treated within one hour after the onset of acute symptoms and a 27% mortality after one hour. Crampton et al⁹ have reported a decrease in coronary mortality in the community; a decrease in ambulance mortality; and a decrease in coronary care unit mortality. Patients are delivered to the hospital earlier and in better condition with increased myocardial oxygenation and arrhythmia control. Nagel et al¹⁰ have raised concern about the small number of long-term survivors among resuscitated patients but espouse the larger dedication of EMS systems designed to respond to all types of acute illness and injury. Such programs are lagging in Connecticut because of inadequate financial support by the Connecticut State Government. The Connecticut Office of Emergency Medical Services has indicated that there may be as many as 3200 preventable deaths each year in the State of Connecticut, which occur as lack of this program. The 1976 budget of \$322,000 allocates \$150,000 to the Regional Programs and the remainder to the administration of the State Program. This budget is inadequate to support and implement the Emergency Medical Services Program as mandated by our legislature.

As a result, qualified personnel have been lost. There are too few inspectors to examine equipment and effectiveness of EMS Programs. A minimum of \$200,000 in additional monies is needed to implement the legislated Rules and Regulations of the 1974 Law. The Connecticut EMS Program is clearly in a state of crisis. The State of Connecticut with three million people is subsisting on a \$0.10 per capita budget administered by eight people. By contrast, the State of North Carolina, with about two million people has received \$0.38 per capita from its state and has an organization of forty-three people.

The nation-wide need to upgrade emergency medical care has been directly addressed by members of the Connecticut State Medical Society, who spotlighted the problems of avoidable deaths due to trauma and heart disease over eight years ago. They led the fight for EMS legislation. They have encouraged those who, by tradition and example, have provided tireless and devoted voluntary care to become part of EMS Systems.

Members of this Society sit on the State EMS Council and on Regional and Local Councils as well. They train personnel, plan, coordinate and evaluate EMS Programs. They integrate community and regional disaster plans. They have helped to implement 911 as the heart of emergency communications sys-

tems. They have participated in the process of Hospital Categorization and in educational programs to train Emergency Physicians, nurses and Emergency Medical Technicians in Basic and Advanced Life Support.

They have initiated secondary school CPR and other first aid programs to educate citizens to the need for an emergency plan of action, to know their emergency telephone number, and the meaning of their role in the EMS system, and what to do until help arrives.

The Connecticut State Medical Society formally supports Emergency Medical Services Systems in Connecticut and urges State Government financial support for its widespread implementation.

Allan A. Brandt, M.D.

*Secretary, CSMS Committee on Accident
Prevention and Emergency Medical Services
Chairman, Milford Hospital Emergency Department
Chairman, Milford EMS Council
Member, Committee on Trauma and Hospital
Categorization
Member, Emergency Cardiac Care Committee,
Connecticut Heart Association*

Meeting Psycho-Social Needs of Cancer Patients

As inroads have been made on cancer survival rates a whole new area of patient need has opened up. The achievement of prolonged lifespan cannot be allowed to suffer due to the tremendous psychological strains cancer places on patients and families. To answer this need, the Connecticut Division, American Cancer Society, under the leadership of M. Patricia Bergin, R.N., Director of Service and Rehabilitation, has initiated a program of patient support groups.

Though the format differs due to local need, these groups are now active in several ACS Units, including Waterbury, Greater Hartford, Middlesex-Meriden-Wallingford, New Haven Metro, and Southern Fairfield County. All have one corresponding aim—to ensure the finest possible quality of life for patient and family.

In small group sessions, patients, and in some areas family members, are free to discuss their innermost concerns, fears, triumphs. Professionals involved as group leaders range from oncologists to nurses, psychiatrists to social workers. Physical problems are largely avoided, with emphasis being placed on emotional support.

As one group leader put it: "I am constantly amazed at what people have to say here that they

couldn't say at home. I think many of them have achieved a sense of strength to go back home and say some of these things." This strength is the dream of all who live with cancer every day of their lives.

To ensure the best possible leadership for these and new groups, the American Cancer Society has arranged for the training of staff and professional volunteers. A series of sessions is being held under the direction of Henry Mandel, M.S.W., and Michelle Webber, M.S.W., of New Haven. Each ACS Unit has been asked to carefully choose an interested and qualified volunteer who will attend this two-day training and follow up along with an American Cancer Society Unit staff person. The first such training has already been held with great success. Physicians interested in further information on ACS support groups or in referring patients should contact the American Cancer Society.

It is no coincidence that the Connecticut Division, American Cancer Society ranked number one in the entire Eastern Area, ACS for 1976 in terms of service to cancer patients. Its programs are among the finest. Now, with continued expansion into this area of psycho-social support, our patients and their families are ensured of even better service from the American Cancer Society.

Edward J. Casey, M.D.

*Chairman, Service and Rehabilitation Committee,
Connecticut Division, American Cancer Society;
Director of Physical Medicine,
St. Joseph Hospital, Stamford*

informed consent. In their study, all patients were found to be unreliable informants regarding the nature of information provided them pre-operatively. They conclude "it is essential to document . . . the details of informed consent . . . since memory of the event is unreliable".

The study usefully raises important questions about three areas: (1) how best to insure that patients understand the information upon which informed consent or informed refusal can be based, (2) how best to insure that patients know and recall that they have received this information, and (3) how best to protect the physician against unfounded accusations that he has not carried out his responsibility of informing the patient. Unfortunately only the third area is addressed in the paper. I would like to comment on the first area.

The authors state that it has been determined that physicians must inform patients of those facts that are material to the decision-making process, in this case, whether or not to undergo non-emergency cardiac surgery. They then state that the informed consent interview was carried out "one or two" days prior to operation. A hospitalized patient that close to surgery is in a poor psychological state to comprehend and assess the risks and options involved. Truly informed consent should allow the patient a realistic opportunity to consider the information given him and to decide to opt for informed consent or for informed refusal. Information imparted so shortly prior to cardiac surgery cannot do this.

In fact an interview carried out under these circumstances, like written materials handed to a patient, may not really fulfill the physician's responsibility to inform his patient. A physician must do his best to be sure that medicine he prescribes is taken, adequately absorbed, and effective. Patients' assurances of compliance cannot substitute for the physician's observations and tests. In the same way, the physician must observe and determine by some reliable means whether the information he presents is absorbed and understood. Physicians notoriously overestimate patients' abilities to comprehend and retain what they are told. The physician must be sure to inform clearly and repeatedly, to test the patient's understanding, and to remedy any deficiencies found. Otherwise the physician, well intentioned though he may be, risks merely playing a charade of informing.

This lead to the observation that the authors never studied the extent to which their patients assimilated the information that was presented to them. If the patients did not understand what they were told it would not be surprising that they did not recall what they were told (or even that they were told). The authors "believe . . . that all patients completely understood the information imparted". Why? Because the patients "were repeatedly asked if (they) understood the explanations". Should we accept this as proof of their comprehension? The findings of the study give one pause. The authors report that "the poorest (recall) of all 20 patients reinterviewed was achieved by a patient who responded authoritatively and expressed no doubts regarding his recollections. Two other patients (near to lower end of the recall scale) were similarly frequently in error but never in doubt". Clearly patients' assertion of knowledge can be no proof of knowledge. A better test of the effectiveness of patient teaching is needed.

Drs. Robinson and Merav have performed a valuable service in bringing our attention to the problems inherent in routinely presenting information to patients and too easily assuming the information is heard, understood and retained.

Marc D. Schwartz, M.D.

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Letters To The Editor

Letters to the Editor are welcomed and will be published, if found suitable, as space permits. Like other material submitted for publication, they must be typewritten *double spaced* (including references), must not exceed 1½ pages in length and will be subject to editing and possible abridgment.

INFORMED CONSENT

To the Editor: In "Informed Consent" (Conn. Med. 42:223-225 1977) Drs. Robinson and Merav present us with research findings designed to underscore the need for defensive practice in the area of

MORE ABOUT SMOKING

To the Editor: Your recent editorial on "Smoking and the Non-smoker" in the March 1977 issue of *Connecticut Medicine* was timely and right on target. As you pointed out the original impetus for the non-smoking campaign was the recognition of the relationship between cigarette smoking and the deleterious health effects including cancer of the lung, heart disease, emphysema, etc.

However, the Tobacco Institute notwithstanding, there is increasing acceptance that non-smokers have the right to breathe clean air, not polluted by smoke from tobacco. Certainly this was considered by the legislature several years ago and Section 1-21b of the General Statutes was enacted prohibiting smoking in a public building while a public meeting was in session. While the data surrounding the health effects of "secondhand smoke" to the healthy non-smoker is somewhat controversial, there seems to be much agreement as to the deleterious effects of smoke from a burning cigarette to those with ischemic heart disease and severe respiratory disease such as asthma and emphysema. A bill being considered by the legislature this year will strengthen the rights of non-smokers in health and educational institutions as well as governmental meetings. You are to be applauded for setting this issue in a clear perspective. The survey "Adult Uses of Tobacco—1975" conducted by Chilton Research Service for the Center for Disease Control, disclosed that more than 3 out of every 4 respondents thought that teachers, doctors and other health professionals should set a good example by not smoking cigarettes. It is further significant that 2 out of 3 smokers felt that members of these groups should set an example. It is too bad our colleagues don't agree for the air is still blue at state and county medical society meetings.

Douglas S. Lloyd, M.D., M.P.H.

Commissioner
State Department of Health
Hartford, CT

CONTROVERSIES ON CORONARY HEART DISEASE

To the Editor: H. Blackburn's article, "Concepts and Controversies about the Prevention of Coronary Heart Disease", *Connecticut Medicine*, January 1977, is repetitious, superannuated, and obfuscating. It contains tables, thoughts, and arguments already published in 1974¹ and reprinted in part in 1975.² Scientific articles should educate the reader. They should not be vehicles for disseminating pragmatic propaganda. The data should be pertinent and current, contrary though they may be to the author's hypothesis. Blackburn quoted almost exclusively a study undertaken in the 1960's by his mentor and collaborator, A. Keys.³ One looks in vain for any reference to Keys' later publications.^{4, 5, 6} in one of which he sought a new risk factor X to explain the 50% lower incidence of ischemic heart disease in European men than in Americans with comparable risk factor exposure. In 1975, Keys stated that the dramatically lower (61%) coronary heart disease mortality of French men compared with U.S. men with almost equal saturated fat intake was due to underdiagnosing of coronary heart death by French physicians. He even attempted to explain the relative scarcity of atherosclerosis in the high milk fat-consuming Masai as being due to unique genetic factors for cholesterol metabolism—unproven and unscientific assumptions, at best.

In 1973,⁶ Keys and co-workers from the University of Minnesota stated that a diet rich in polyunsaturates reduces serum cholesterol

by 17%. His study used 3 groups of only 12 men each for 21 and/or 14 days. This puny evidence is now widely advertised, televised, and highly recommended to all Americans. Yet Blackburn of the same institution, in 1977, sees no reason to distort the American diet by an excess of polyunsaturates. He disavows thereby the recommendations of "prudent diet" (10% saturated, 10% monounsaturated, and 10% polyunsaturated) by the Inter-Society Report, updated in 1975.⁷ (Blackburn referred to the Inter-Society's New York address. He seems to be unaware that its headquarters moved, with the American Heart Association, to Dallas late in 1975.) The scientific accuracy of this highly praised report was severely criticized by Werko⁸ and by me.^{9a, b, c}

Blackburn rightfully questions, "Is it reasonable to expect a 10, 25 or 50% decrease by intervention on people at such an advanced stage of a multi-factorial and socio-cultural phenomenon?" He forgets that the Inter-Society Report answers his question with definite numbers: 10% reduction in serum cholesterol level of the United States population is estimated to yield a 24.4% decrease in coronary heart disease incidence, a 25% reduction produces a 53.5% decrease, and a 50% reduction yields 84.2% less incidence. I questioned the lack of biological reality of these simplistic, confusing, and naive calculations by a biostatistician.^{9a} Blackburn seemed not to have these doubts when he recommended the millions of dollars to be spent on the MRFIT (Multiple Risk Factor Intervention Trial) program of which he is a principal investigator. Does he now prepare us and himself for an easy way out of his dilemma in the knowledge that mean plasma cholesterol values are, in reality, much lower than we were led to believe by the Framingham study?¹⁰

Kurt A. Oster, M.D.

Bridgeport, CT

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CONNECTICUT MEDICINE

To the Editor: It is impossible not to read your fascinating Journal. Keep it up! Suggest you try to get Springfield, Massachusetts, MDs, as subscribers.

Bernard S. Dignam, M.D.

Enfield, CT
Hartford County Medical Society
Staff of Mercy Hospital
Springfield, MA

A SCHISTOSOMIASIS VACCINE

Progress in immunization against schistosomiasis, an unconquered parasitic disease, has been reported by Dr. George V. Hillyer, head of a research group at the University of Puerto Rico.

Appearing in the December 1976 issue of *Federation Proceedings*, monthly publication of the Federation of American Societies for Experimental Biology, is the report, "Can we Vaccinate Against Schistosomes?", written by researchers of the Minority Biomedical Support Program which is funded by NIH's Division of Research Resources.

Schistosomiasis is a disease of man and animals caused by blood flukes (parasitic worms) of the genus *Schistosoma*. The parasites causing human disease are found in the Orient (an estimated 200 million Chinese are infected), portions of Africa including The Nile, South America especially Brazil, and some of the islands of the Caribbean. It is estimated that 300,000 persons are infected in Puerto Rico. Infection does not occur in the United States, but is present in the bloodstream of some immigrants entering the country.

It takes three to make a schistosomiasis infection—mammalian host, intermediary snail host, and the parasitic schistosome (a blood worm or fluke).



Fork-tailed larva (400 microns long) can penetrate the skin and eventually turn into mature schistosomes. Researchers at the University of Puerto Rico, supported by NIH's Division of Research Resources, are making progress in the effort to develop a vaccine against schistosomiasis—a parasitic disease affecting over 300,000 persons on the island.

Transmitted by excretion, a schistosome egg passes through the intestine of an infected mammalian into fresh water and hatches into a larval stage called a miracidium. The miracidium infects a specific type of snail, and after several developmental changes in the snail, the parasite evolves into a fork-tailed larva

known as cercaria. When the cercaria leaves the mollusk, it propels its way through the water in search of a mammalian host.

When it makes contact with a human being, it penetrates the skin and enters the body. The cercaria eventually turns into mature schistosomes which live in the bloodstream. The parasite, in its adolescent stage, matures and mates, and the female lays its eggs. The adult worms remain in the blood vessels surrounding the intestinal tract or urinary bladder, their eggs traveling through the bloodstream to various organs of the body, particularly the liver.

The victim generally experiences itching, pain, weakness, and a shortened life span.

It has been determined that when animals and man are infected with schistosomes, they acquire resistance to re-infection, and the resistance is immunologic in origin. Apparently the cells produce a toxicity which is induced by an antigen.

Dr. Hillyer's group has been conducting long-range studies on immunology induction in mice and hamsters before infection. In recent laboratory experiments, the researchers have found a complex of polyadenilic-polyuridylic acid (poly AU) to be a powerful stimulant of antibody production when inoculated into animals together with an antigen.

By use of *Fasciola* antigens (from another kind of fluke) combined with one injection of poly AU, the researchers achieved a 67 percent reduction in worm burden (schistosome infection) in mice. When two inoculations of poly AU were used, the worm burden reduction was 74 percent, according to Dr. Hillyer.

They also report that mice immunized with *Fasciola* antigens had four-fold or higher titers of antibodies to schistosomes than mice infected with schistosomes but not immunized.

Concluding that *Fasciola* antigens prime the host to have a secondary reaction when infected with schistosomes, the current work of the Minority Biomedical Support group at the University of Puerto Rico is now directed toward purifying the antigens involved in this protection.

The researchers are optimistic that eventually a vaccine can be prepared which will give total protection against this parasitic disease now so prevalent in China, Africa, South America, and Puerto Rico.

This study was supported by NIH's Division of Research Resources H.E.W. Public Health Service, Bethesda, M.D., January 1977.

FROM THE EXECUTIVE DIRECTOR'S OFFICE

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Scientific Activities*

Summary of Actions

Council Meeting

Thursday, May 12, 1977

I. Attendance

Present were: Drs. Freedman, Kamens, Backhus, Johnson, Ragland, Spitz, Hess, Bradley, Fabro, Van Syckle, Sadowski, Harkins, James, Mendillo, Krinsky, Sonnen, Whalen, E. Beck, Horrax, Magram, Barrett and Zlotsky.

Also present were: Mrs. Lindquist, Mr. Brunell and Mr. Sweeney.

Absent were: Drs. Friedberg, Grendon, Canzonetti, Cramer, McGarry, R. Beck, Vidone, Eslami, Parrella, Middleton. Dr. Richards, Executive Director.

Organizational Meeting

Due to the absence of the President, the organizational meeting of the Council for 1977-78 was called to order by the President-elect, Jerome K. Freedman. Following some opening remarks and the introduction of Council members, elections of a Chairman and a Vice-Chairman of the Council for 1977-78 were held. Those elected: Chairman—David A. Grendon, Sharon; Vice-Chairman—Guy W. Van Syckle, Danbury. Dr. Grendon being absent, Dr. Van Syckle took the chair.

II. Routine Business

Life Memberships

It was VOTED to approve applications for Life Membership received from the following Active Members:

Milton L. Jennes, Waterbury
James H. Kelleher, Norwich
Harry R. Newman, New Haven
Martin C. Rogers, Stamford
Stephanie Z. Roth, New Haven
Paul Teiger, Waterbury
Albert J. Trimburt, Bethel

Date of Next Meeting

The Vice-Chairman scheduled the next meeting of the Council for Wednesday, June 8, 1977.

III. Old, New and Special Business

Connecticut Ambulatory Care Study

The Council considered several matters relating to the Ambulatory Care Study and took the following actions:

(a) *Ownership of Data*: VOTED to approve the statement of the CACS Advisory Committee, made at its meeting on June 10, 1975, "that the data is the property of CSMS" and to so inform the Advisory Committee.

(b) *Storage and Physical Control of CACS Data*: VOTED to instruct staff to investigate possible places and costs for storage of CACS data, including in this investigation all pertinent details concerning ownership of data and rights concerning limiting of accessibility, and to report back to the Council at its next meeting.

(c) *Plan to Keep Data Open for Subsequent Studies*: VOTED that, on completion of the study, a successor group to the Advisory Committee of CACS should be appointed by the Council of CSMS from, but not limited to, nominees recommended by the Committee on Statewide Medical Planning. These nominees will include representatives of the Society, of the participating hospitals, and a representative from each medical school in Connecticut.

(d) *Request for Use of CACS Data*: VOTED to authorize Mrs. Ruth Riedel to use the CACS data for her PH.D. thesis to the extent requested in her letter of May 10, 1977 to Dr. Freedman.

Dates and Site for 1978 and 1979 Annual Meeting

It was VOTED to approve the Hartford Hilton Hotel for the site of the annual meeting and the following dates: 1978—Wednesday and Thursday, May 3, 4; 1979—Wednesday and Thursday, May 2, 3.

It was further VOTED to instruct the Subcommittee on Annual Meeting Arrangements to study and evaluate the annual dinner as to format and necessity for holding such a dinner.

Guidelines for the Health Care of the Elderly

It was VOTED to approve as CSMS policy a sub-

(continued on page 388)



RECENT CHANGES

federal register

Providing Drug Information to Physicians

Informational Bulletin #433-76

National Health Insurance

special report Malpractice Insurance:

drug bulletin

Health care doesn't need more red tape

Drug firms challenge 'MAC' rules

Drug Substitution

The Common Denominator of Health Progress RESEARCH

Mailgram

THERE ARE A LOT OF PEOPLE GETTING BETWEEN YOU AND YOUR PATIENT.

Medicine today is in the spotlight, subjected to all kinds of scrutiny. Your control over patient therapy is being monitored, judged and occasionally abrogated, sometimes by unknown third parties.

The worry is that in the wake of this focus, the relationship between you and your patient will be weakened, without offsetting benefits. Consider three examples:

Drug substitution In most states, pharmacy laws, regulations or professional custom stipulate that your non-generic prescriptions be filled with the precise products you prescribe. But in the last five years, a dozen or more State laws have been changed, permitting the pharmacist in most cases to select a product of the same generic drug to fill any prescription.

Ironically, this dilution of physician control has taken place against a background of growing evidence that purportedly equivalent drug products may be inequivalent, since neither present drug standards nor their enforcement are optimal. In fact, the FDA itself says it has not enforced the same standards for hundreds of "follow-on" products that it had applied to the original NDA approvals. Thus physician control over patient therapy is being eroded with a risk that patients may be exposed to drugs of uncertain quality.

The major advertised claim for substitution is reduced prescription prices for consumers. Yet no documentation of any significant savings has been produced.

MAC Maximum Allowable Cost, MAC for short, is a Federal regulation designed to cut the Government's drug bill by setting price ceilings for drugs dispensed to Medicare and Medicaid patients. Unless the prescriber certifies on the prescription that a particular product is medically necessary, the Government intends to pay only for the cost of the lowest-priced, purportedly-equivalent,

generally-available product. The effect of the program may be that elderly and indigent patients will be restricted to products which someone in Washington believes are priced right. Practicing doctors will have little to say about administration of the program, since Government will have absolute authority to make its choices stick.

The drug lag The future of drug and device research depends upon a scientific and regulatory environment that encourages therapeutic innovations. The American pharmaceutical industry annually is spending more than \$1 billion of its own funds and evaluating more than 1,200 investigational compounds in clinical research. Disease targets include cancer, atherosclerosis, viruses and central nervous system disorders, among others. But there is a major barrier to the flow of new drugs to your patients: The cost of the research is more than ten times what it was, per product, in 1962; and whereas governmental clearance of new drug applications took six months then, it commonly consumes two years now.

The FDA needs adequate time, of course, to consider data. But it is equally clear that the present approval process contributes to needless delay of needed therapy. That's why the increased efficiency of the drug approval process is vital to all our futures.

If these issues concern you, we suggest that you make your voice heard—among your colleagues and your representatives in State legislatures and in Washington.

It could make a difference in your practice tomorrow.

Pharmaceutical Manufacturers Association
1155 Fifteenth Street, N.W., Washington, D.C. 20005



(continued from page 385)

ject document prepared by the Judicial Committee and to suggest to the Editor of *Connecticut Medicine* that this material would be appropriate for publication in the Journal as general information; that copies be mailed to those health care facilities dealing with elderly patients; and that the Guidelines be used as a basis for a press release. It was further VOTED to send a copy to the Governor.

Attendance—Meeting of House of Delegates 4/27/77

Following discussion, it was VOTED to receive as information a staff-prepared analysis of attendance at the Annual Meeting of the House of Delegates by Council members and County Association Delegates. It was further VOTED that copies of the analysis be sent, together with a list of the delegates attending, to each of the County Associations, and this be done following all meetings of the House of Delegates. In a related action, it was VOTED to request staff to note the time that each delegate registers following the Call to Order of the meeting.

State Professional Standards Review Council

It was VOTED to receive as information a subject resolution from the Fairfield County Medical Association "urging the Council of CSMS to instruct its delegates to the PSR Council to vote for the right of alternates to participate in and vote upon matters before the PSR Council if the primary member is unable to attend." Following considerable discussion, it was VOTED to express sympathy with the purpose of the FCMA resolution but to inform FCMA that, according to CSMS members serving on the PSR Council, regulations in the PSRO Program Manual do not provide for voting by other than primary PSR Council members.

Committee for Better Medicare Assignment Rate

Dr. Van Syckle reported that it had been brought to his attention that Congressman "Toby" Moffett had organized a Committee for Better Medicare Assignment Rate in which Commissioner William R. Ratchford, Commissioner of the Department of Aging, has now expressed some interest, and that probably CSMS should be represented on this Committee. It was VOTED that the Vice-Chairman of the Council approach Connecticut General to seek information as to the mechanism by which the Society could obtain

representation on the Committee and to report back to the Council at the next meeting.

Inaugural Address of the President

It was VOTED to authorize the Vice-Chairman and President to appoint a Subcommittee to study the proposal outlined in the President's inaugural address which would set up a series of seminars on medical costs and the factors influencing these costs.

Meeting Re Medicaid Payments

Jerome K. Freedman and Hilliard Spitz reported on a meeting held with members of the Governor's staff, the Commissioner of the Department of Social Services, members of the CSMS Liaison Committee with the Department of Social Services, and the President of the Society, concerning payment of physicians under the Medicaid Program. Their report included a discussion of substandard payments made to physicians under the Medicaid program and the possibility of returning to usual and customary charges. CSMS representatives pointed out to the group that it was felt that the State could reduce costs if physicians were allowed to charge their usual and customary fees for services rendered in their offices as opposed to the charges made in hospital and emergency room settings where a great many Medicaid recipients were presently being treated. Following the presentation, a motion was made to authorize the Liaison Committee with the Department of Social Services to proceed with ambulatory services. It was finally VOTED to table this motion until the matter was pursued further.

Mrs. George E. Roch, Willimantic

It was brought to the attention of the Council that Mrs. George E. Roch, widow of a former Councilor from Windham County and past-president of the Auxiliary to the Connecticut State Medical Society, had died. It was VOTED to send a letter of condolence to Mrs. Roch's sons.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on May 12, 1977. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

OBITUARIES

W. BRADFORD WALKER, M.D. 1895–1977

Dr. W. Bradford Walker was born in New Haven, November 30, 1895. He graduated from Yale undergraduate college and, in 1920, from Yale Medical School, where, in a rare example of prognostic accuracy, the faculty awarded him the Parker prize as the "fourth year student who . . . has shown the best qualifications for a successful practitioner". Following a rotating internship at Hartford Hospital, he came to Cornwall in 1923 as physician to the 50 boys of Rumsey Hall School, then located in that town, and opened an office for the private practice of medicine which was not to close for 54 years. During that time he truly became physician to Northwest Connecticut, serving patients from as far away as New York State to the west, the Massachusetts state line to the north, Torrington and Litchfield to the east, and Washington and Kent to the south. It is estimated that he delivered over 6,000 infants.

Dr. Walker's activities extended well beyond the limits of his exhausting practice. At various times he was chief of staff at Charlotte Hungerford Hospital, president of the Litchfield County Medical Society, and president of the Connecticut State Medical Society. He served on numerous state medical committees and commissions, including the Connecticut Public Health Council and Connecticut Health Association. Closer to home, he served as medical examiner and health officer for the towns of Cornwall, Goshen, and Warren, and for over 35 years, was endorsed as Judge of Probate for Cornwall by both political parties. His was the driving force behind the creation of the W.B. Walker Community Health Association.

Dr. Walker was a fellow of the American College of Physicians, and, until his eyesight began to fail, he kept his professional skills sharp by avid consumption of the medical literature. In the early thirties, he recognized the potentials of electrocardiography, went away for a course in ECG interpretation, bought a machine, and introduced electrocardiography to northwestern Connecticut.

Impressive as this statistical analysis of his activities may be, it fails to convey the essence of his worth and value, which lies rather in the warm and devoted relationships he established with his patients. This is much harder to get at, and rather than try, I have taken the liberty of letting his patients speak for themselves. Following are excerpts from letters to the editors of various local newspapers. From the *Lakeville*

Journal, Polly Calhoun writes: "How shall we remember, love, and mourn the memory of Brad Walker, M.D.? For over 50 years his patients in Cornwall and surrounding towns lived in security, for we knew that in the rising panic of acute illness in the middle of the night, Brad would come, make an uncannily correct diagnosis, decide the treatment, which usually produced the beginning of a cure, and stay until anxiety lessened". And, from the same paper, Dorothy VanDoren: "He will always live with us as long as we live; a good, knowledgeable doctor who read the medical journals faithfully, a loving friend, a merry companion. There was never a time when we needed him that he did not come—not one time. If doctors have changed, he did not change. And our love for him and memory of him will not change either. He was an essential part of our lives and he will be, always. And, in the *Torrington Register*, from Doris Kalinowski: "His greatness and I don't hesitate to use that word, lay in his utter and absolute devotion to medicine and ministering to people. He had great integrity, and the utmost respect for life. Money was very low on his list of priorities; an endearing quality in anyone, but a qualification for sainthood in a doctor."

To his wife, Katharine Walker, and his three sons, Edward, W. Bradford, Jr., and Dr. Tom Walker, we extend our sympathy and share their sorrow in this common loss. Beyond this, we should give thanks for the legacy of good will towards our profession that he has left us; a legacy we would do well to cherish and nurture.

C.H. Huvelle, M.D.

WINFIELD E. WIGHT, M.D. 1895–1977

Dr. Winfield E. Wight, of Thomaston, Connecticut died February 2, 1977 at the age of 81, one year after retiring from active practice. He was born in Milan, New Hampshire on April 8, 1895. Dr. Wight was a graduate of Gould Academy, Bowdoin College and Bowdoin Medical School.

After an internship and residency at Waterbury Hospital, he settled in Thomaston serving the community as surgeon and general practitioner. He was attending surgeon at Waterbury Hospital for many years.

Dr. Wight served in the Medical Reserve Corps and the U.S. Public Health Service Reserve. He was Medical Examiner and Health Officer in Thomaston for many years.

He was a fellow of the American College of Surgeons and a member of the Litchfield County Medical Association, the Connecticut State Medical Society and the A.M.A.

He was outstanding in his contributions to the Thomaston community. He served on the school board, finance board and as president and chairman of the Thomaston Savings Bank. He was a member and past president of the Thomaston Rotary Club and a member of many other local organizations. He was an honorary Deacon of the First Congregational Church and a 32nd degree Mason.

Dr. Wight was a dedicated and devoted physician, sensitive and sympathetic to his patients whom he served unselfishly with understanding and compassion. His death is a great loss to the community which he served so faithfully for so many years.

During his busy life he and his wife traveled extensively. He was an enthusiastic fisherman. He had a great sense of humor and always enjoyed exchanging stories with his friends.

He is survived by his widow, Mrs. Anna (Ebert) Wight of Thomaston; a son, Winfield E. Wight, Jr., of St. Petersburg, Fla.; a daughter, Mrs. Clifford T. Conklin of Thomaston, and seven grandchildren.

Daniel P. Samson, M.D.

In Memoriam

Bennett, Alfred M., University of Illinois, 1947. Dr. Bennett was a practicing cardiologist in the Fairfield area for the past three years. He served in the U.S. Army as Captain from 1951 to 1953, in the Korean War. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society. Dr. Bennett died March 9, 1977, at the age of 51.

McIlroy, Patrick, Queens University, 1921. Dr. McIlroy was a pathologist in the Fairfield area since 1937. He served with the medical corps of the Canadian Army during World War I and from 1927 to 1936 was assistant director and pathologist of the Von Wedel Laboratory in Westchester County. He was also the pathologist for Sing Sing Prison. In 1936 he became the first pathologist on Danbury Hospital's staff and had a private practice in Redding for several years, was director of the Columbia Medical Laboratory in Bridgeport for two years and had his own clinical laboratory in Danbury for nearly 10 years. He moved to Danbury, New Hampshire, in 1967 where he was semi-retired with a small private practice before being called back to duty as a pathologist at Franklin Regional Hospital in Franklin, New Hampshire. He served there until 1973 when illness forced his retirement. Dr. McIlroy died March 14, 1977, at the age of 84.

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PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiry of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511, (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine*.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

Dermatology: Two fully-equipped offices available, one in New Britain and one in Bloomfield. Contact 677-7612 or 225-6464.

Family Medicine: Long established practice for sale by estate of deceased physician in Fairfield County (Bethel) suburban community. EKG, x-ray and other office equipment and furnishings and rented premises also available. Contact Attorney Alan D. Mandl, 1036 Walnut Street, Newton-Highland, Mass. 02161. (617-965-4158).

Family Practice: One of fastest growing suburban communities in Connecticut. Convenient to UConn and Yale Medical Centers. Financial assistance considered. Excellent community hospital with multiple specialty back-up. Contact CSMS.

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Internal Medicine: Third Internist desired for active two man practice in S.E. Ct. shoreline town. Prefer general internist interested in patient care. Early availability preferred. Write CSMS-IM.

Occupational Medicine: (2 openings) Physicians needed to perform professional medical services in an occupational health clinic for state employees. Both positions require a license to practice medicine and surgery in Connecticut. Submit resume to: Mr. John J. Crowley, Personnel Administrator, Department of Health, 79 Elm Street, Hartford, CT. 06115.

OB/GYN: Contact Mr. H.L. Green at Winsted Memorial Hospital, Winsted, CT 06098. 379-3351 ext. 270 for details.

Pediatrics: Excellent partnership opportunity in attractive mid-Connecticut community. Contact CSMS.

Pediatrics: Board certified or eligible pediatrician wanted by September 1977 to join busy pediatric group in upper Fairfield County. Yale-affiliated hospital. Contact: Pediatric Associates, 84 Locust Avenue, Danbury, CT. 06810. 203-744-1680.

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PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

Anesthesia: 33 years of age with Connecticut license wishes group practice in a medium sized community. Eligible. National Boards. Residency at Yale-New Haven Hospital. Available July 1977. J. John Barbieri, M.D., 123 York St., 22L, New Haven, CT. 06511

FAMILY MEDICINE

July '77. Age 37. Presently doing surgical res. but interested in starting GP. Solo, grp. or assoc. practice preferred. Applied for Connecticut license. Mohammed I. Alvi, M.D., St. Barnabas Medical Center, Old Short Hills Road, Livingston, NJ 07039.

July '77. Age 28. M.D. from Univ. of Pittsburgh. Int. and res. at York Hosp. Nat'l. bds., elig. Will consider temporary ER work. Gary M. Cummins, M.D., 1001 S. George Street, York, PA 17402.

July '77. Age 46. Connecticut license. Int. and res. in England. Interested in FM or ER or ambulatory or primary care positions. Syed A.A. Shah, M.D., 94-48 A Alstyne Avenue, Elmhurst Queens, NY 11373.

INTERNAL MEDICINE

July '77. Age 28. Int. from Genesee Hosp., res. at Rochester. Nat'l. bds., elig. Within 10-20 mile radius of Farmington. Minimal financial investment. Thomas P. Chairmont, Jr., M.D., 112 Berkeley Street, Rochester, NY 14607.

July '77. Age 32. Currently on the faculty of UConn. M.D. from Johns Hopkins. Solo or institutional practice. Younus F. Masih, M.D., 55 Elizabeth Street, Box 218, Hartford, CT 06105.

July '77. Age 35. M.D., int., res. and fellowship, London, England. Elig. Institutional or industry practice. Large or medium community desired. Brahm D. Sethi, M.D., Fern Towers, #305, 50 S. Munn Avenue, East Orange, NJ 07018.

Cardiology: July '77. Age 38. Cert. Mainly interested in IM and if facilities exist some clinical cardiology also. Nairvittil Chandrasekharan, M.D., Bergen Pines County Hospital, Paramus, NJ 07652.

OB/GYN

July '77. Age 33. FLEX. Elig. Prefers solo practice in small or medium community close to a city. Res. and int. Montefiore Hosp., NY. R. George Cherian, M.D., 3450-21N Wayne Avenue, Bronx, NY 10467.

July '77. Age 32. FLEX. Cert. Fellowship at Notre-Dame Univ., Canada. Solo, group or assoc. practice. Said Papas, 715 135h Avenue, #334. Sherbrooke, Quebec, Canada J1E 2Y7.

OPHTHALMOLOGY

July 1977. Age 32. Bd. elig. Solo, group or associate practice. Also interested in purchasing a practice. M.D. from Albert Einstein. Howard Z. Marton, M.D., 1010 Old Towne Dr., St. Louis, MO 63132.

May 1977. Age 30. Bd. cert. Group or associate practice in medium sized community. M.D. from McGill. Robert Wener, M.D., 142 Aldred Place, Hampstead, Quebec H3X 3J3.

Ophthalmology: FLEX. Would like to join an associate or multi-specialty group in a medium sized town. 35 years of age. Available July 1977. Appireddy Bommareddy, M.D., 9293 Pickwick East, Taylor, MI 48180.

Ophthalmology: Interested in areas closer to New York, will consider all areas. Solo, group or buying a practice. 30 years of age. National Boards. Eligible. Available July 1977. Theodore M. Ingis, M.D., 430 E. 63rd St., Apt. 3-L, New York, NY 10021.

Ophthalmology: Available July 1977. 31 years of age. Certified, National Boards. Presently in practice. Group or associate practice in medium sized community. M.D. from University or Rochester. Gary S. Clorfeine, M.D., 541-B Winans Road, West Point, NY 10996.

Ophthalmology: 31 years of age. Connecticut license. Presently in practice wishes solo or associate practice in Connecticut. National Boards. Eligible. M.D. from State University of New York. Available July 1977. Sigmund S. Gould, M.D., 4132 Wyndybrown Drive, Portsmouth, VA 23703.

ORTHOPEDIC SURGERY

July 1977. Age 29. Bd. elig. Solo or associate practice in medium or small community. M.D. from NY Med. College. Int. and res. at Montefiore Hosp., Bronx. Roy B. Friedenthal, M.D., 6049 Huxley Avenue, Bronx, NY 10471.

OTOLARYNGOLOGY

July 1977. Age 34. FLEX. Solo, group or associate practice in medium community. Fellow at Lenox Hill Hosp., NY. Jagadish D. Navare, M.D., 3409 150th St., Flushing, NY 11354.

PATHOLOGY

Three months notice. Age 36. Nat'l Bds. FLEX. Int. Manchester Memorial Hosp., Conn. Res. Baptist Hosp., Winston-Salem, NC. Group, associate or institutional practice in medium community. Ramesh P. Dave., M.D., 18 Terry Dr., Jacksonville, IL 62650.

Available now. Age 32. Bd. elig. Res. Norwalk Hospital, Conn. Licensed in Conn. Full-time position in a group or associate practice, but willing to work part-time or cover weekends provided the place is a commutable distance from Rockville, Conn. Contact-CSMS-Path.-SMD.

PEDIATRICS

July '77. Age 29. Cert. in Pediatrics and elig. in allergy and immunology. Fellowship at Long Island College Hosp., NY. Seetharaman Adimoolam, M.D., 49 E. 40th Street, Brooklyn, NY 11203.

Available now. Age 29, FLEX. Elig. Institutional, industrial or associate practice in large or medium community. Res. and presently fellowship at St. Raphael's Hosp., New Haven. Contact CSMS-Ped. AKU.

Surgery: July '77. Age 36. Elig. Res. at Jewish Hosp., Ohio, Variety Children's Hosp., Florida and presently at St. Joseph's Hosp., Colorado. Will consider all opportunities in Ped.-Surg. Contact CSMS-Ped.-SRP.

PSYCHIATRY

(Husband-wife team) August '77. Part-time. Cert. gen. psy., elig. child psy. Res. and fellowship at Mt. Sinai Hosp., Elmhurst, NY. Consider all types of practice. Angeline C.N. Desai, M.D. and Sureshchandra N. Desai, M.D., King Edward Building, 79-11, 41st Avenue, Apt. B4-11, Elmhurst, Queens, NY 11373.

September '77. Age 38. M.D. from Univ. of Ottawa. Res. at Montreal Gen. Solo or group practice desired. Experience as Director of Day-Care Center as well as group therapy and resident supervision and tutoring. J.P. Augustine Noonan, M.D., 1640 Montpelier, St. Bruno, Quebec, Canada J3V 4P5.

SURGERY

July '77. Age 31, FLEX. Elig. M.D. from Damascus Univ. Int. New Britain Gen. Hosp., Conn. Res. Univ. of Conn. Group or assoc. practice in large or medium community. Mohammad Amawi, M.D., 1213 13th Ave., Apt. 1321, Dodge City, KS 67801.

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August '77. Age 33. Nat'l. bds. Cert. Presently serving in Army. M.D. from Columbia. Int. and res. at Roosevelt Hosp., NY. Group or assoc. practice desired. Experience in gastroscopy and colonoscopy and vascular surgery. Kenneth G. Benoit, M.D., 5th General Hospital, APO NY 09154.

August '77. Age 34. Nat'l. bds. Cert. M.D. from Harvard. Res. at Univ. of California. Solo, group or assoc. practice desired. General surgery including thoracic and vascular. Contact CSMS-Surgery-PEG.

July '77. Age 36. Elig. All education from Cairo Univ., Egypt. Solo, group or assoc. practice in large or medium community. Presently Chief surgical resident at Grace Hosp., Michigan. Ahmad S. Hassan, M.D., 841 Barrington, Grosse Pointe Park, MI 48230.

July '77. Age 33. Res. at Norwalk Hosp., CT. Presently doing res. program at Morristown Mem. Hosp., NJ. Assoc. practice in med. community. Norman Val B. San Agustin, M.D., 146-C Franklin Street, Morristown, NJ 07960.

UROLOGY

Available now. Age 44. Elig. Connecticut license. M.D. from Queens Univ., Canada. Int. and res. while serving in Navy. Also res. at Upstate Med. Center, NY. Robert P. Heldt, M.D., 332 Broadway Avenue, W., Watertown, NY 13601

July 1977. Age 31. Bd. elig. M.D. and res. from Columbia. Solo or associate practice in large or medium community. Presently on active duty. Steven L. Sholem, M.D., P.O. Box 335, Litchfield Park, AZ 85340.

Availability-Negotiable. Age 30. Bd. elig. M.D., int., res. and fellowship all at Boston Univ. Med. Ctr. Special interest in neurogenic bladder problems. Group, associate or institutional practice. Mike B. Siroky, M.D., 35 Howard St., Newton, MA 02158.

July 1977. Age 32. Bd. elig. M.D. from Vanderbilt. Int. at Yale-New Haven Hosp. Fellowship at Mayo Graduate School. Presently doing res. program at Univ. of Kentucky. Group or associate practice in large or medium community. Stephen J. Sweitzer, 350 Curtain Dr., Lexington, KY 40503.

July 1977. Age 35. FLEX. Bd. elig. Solo, group, associate or institutional practice in large or medium community. Mohammad T. Tavassoli, M.D., 30 Pryer Lane, Larchmont, NY 10538.

July 1977. Age 29. Bd. elig. M.D. from Harvard. Group or associate practice in large or medium community. Will consider academic affiliation. Robert K. Vinson, M.D., 1004 University, Ann Arbor, MI 48104.

July 1977. Age 31. Bd. Elig. M.D. from Chicago Med. School. Res. at Mt. Sinai Hosp., Chicago. Solo, group or associate practice. Robert J. Winstein, M.D., 2003 W. Touhy Ave., Chicago, IL 60645.

July 1977. Age 29. Bd. elig. M.D. and res. from SUNY-Downstate. Group or associate practice in large or medium community. Stuart Zykorie, M.D., 152 Baltic Street, Brooklyn, NY 11201.

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